PATENT
Customer Number 22,852
Attorney Docket No. 08157.0014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
David VALE et al.	)	Group Art Unit: 3731
	)	
Application No.: 09/985,820	)	Examiner: Uyen T. Ho
	)	
Filed: November 6, 2001	)	
	)	
For: FILTER ELEMENT FOR EMBOLIC PROTECTION DEVICE	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

CLAIM FOR PRIORITY

Under the provisions of Section 119 of 35 U.S.C., Applicants hereby claim priority from, and the benefit of the filing date, of International Patent Application No. PCT/IE99/00033, filed May 7, 1999, for the above identified U.S. patent application.

In support of Applicants' claim for priority, a certified copy of the priority application is filed herewith.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 15, 2004

By: _____
Roland G. McAndrews
Reg. No. 41,450

721558_1.DOC

Patents Office
Government Buildings
Hebron Road
Kilkenny

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	PCT/IE99/00033
Date of Filing	7 May 1999
Applicant	SALVIAC LIMITED, an Irish company of 39-40 Upper Mount Street, Dublin 2, Ireland.

Dated this 17 day of August 2001.

Clare O' Reilly

An officer authorised by the
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PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No. PCT/IE 99/00033

International Filing Date - 7 MAY 1999 (07.05.99)

IRISH PATENTS OFFICE
PCT INTERNATIONAL APPLICATION

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference (if desired) (12 characters maximum) SALV11/C/WO

Box No. I TITLE OF INVENTION

"Embolic Protection Device"

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

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☐ This person is also inventor.

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This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

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This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

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This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

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☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

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This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: IE

State *(that is, country)* of residence: IE

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- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

GILVARRY, Michael
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This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: IE

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This person is applicant for the purposes of:
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This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

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Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- [ ] all designated States
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PCT/ 99/00033

Box No. V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes, at least one must be marked)*:

Regional Patent

- ☒ AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- ☒ AL Albania
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- ☒ CZ Czech Republic
- ☒ DE Germany ..and utility model
- ☒ DK Denmark ..and utility model
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- ☒ SD Sudan
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- ☒ SG Singapore
- ☒ SI Slovenia
- ☒ SK Slovakia
- ☒ SL Sierra Leone
- ☒ TJ Tajikistan
- ☒ TM Turkmenistan
- ☒ TR Turkey
- ☒ TT Trinidad and Tobago
- ☒ UA Ukraine
- ☒ UG Uganda
- ☒ US United States of America
- ☒ UZ Uzbekistan
- ☒ VN Viet Nam
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Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☒ ..ZA South Africa
- ☒ ..AE United Arab Emerates
- ☐

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

PCT/IE 99/00033

Box No. VI. PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1)				
item (2)				
item (3)				

☐ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): _____

* *Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):*

ISA / EP

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets:**

request	: 4
description (excluding sequence listing part)	: 31
claims	: 8
abstract	: 1
drawings	: 26
sequence listing part of description	:
Total number of sheets	: 74

This international application is **accompanied** by the item(s) marked below:

1. ☒ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☒ copy of general power of attorney; reference number, if any: 39802, 40018, 39845
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify)*:

Figure of the drawings which should accompany the abstract: Fig. 46

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

John O'Brien

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1. Date of actual receipt of the purported international application: 07 MAY 1999 (07.05.99)	2. Drawings: ☒ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): ISA / EP	6. ☐ Transmittal of search copy delayed until search fee is paid.

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Date of receipt of the record copy by the International Bureau:

"An Embolic Protection Device"

Introduction

The invention relates to an embolic protection device.

The term "STROKE" is used to described a medical event whereby blood supply to the brain or specific areas of the brain is restricted or blocked to the extent that the supply is inadequate to provide the required flow of oxygenated blood to maintain function. The brain will be impaired either temporarily or permanently, with the patient experiencing a loss of function such as sight, speech or control of limbs. There are two distinct types of stroke, haemorrhagic and embolic. This invention addresses embolic stroke.

Medical literature describes caroitid artery disease as a significant source of embolic material. Typically, an atherosclerotic plaque builds up in the carotid arteries. The nature of the plaque varies considerably, but in a significant number of cases pieces of the plaque can break away and flow distally and block bloodflow to specific areas of the brain and cause neurological impairment. Treatment of the disease is classically by way of surgical carotid endarterectomy whereby, the carotid artery is cut and the plaque is physically removed from the vessel. The procedure has broad acceptance with neurological complication rates quoted as being low, somewhere in the order of 6% although claims vary widely on this.

Not all patients are candidates for surgery. A number of reasons may exist such that the patients could not tolerate surgical intervention. In these cases and an increasing number of candidates that are surgical candidates are being treated using transcatheter techniques. In this case, the evolving approach uses devices inserted in the femoral artery and manipulated to the site of the stenosis. A balloon angioplasty catheter is inflated to open the artery and an intravascular

stent is sometimes deployed at the site of the stenosis. The action of these devices as with surgery can dislodge embolic material which will flow with the arterial blood and if large enough, eventually block a blood vessel and cause a stroke.

It is known to permanently implant a filter in human vasculature to catch embolic material. It is also known to use a removable filter for this purpose. Such removable filters typically comprise umbrella type filters comprising a filter membrane supported on a collapsible frame on a guidewire for movement of the filter membrane between a collapsed position against the guidewire and a laterally extending position occluding a vessel. Examples of such filters are shown in US 4723549, US 5053008, US 5108419, WO97/17100 and WO 98/33443. Various deployment and/or collapsing arrangements are provided for the umbrella filter. However, as the filter collapses, the captured embolic material tends to be squeezed outwardly towards an open end of the filter and pieces of embolic material may escape from the filter with potentially catastrophic results. More usually, the filter umbrella is collapsed against the guidewire before removal through a catheter or the like. Again, as the filter membrane is collapsed, it will tend to squeeze out the embolic material. Further, the umbrella filter is generally fixed to the guidewire and any inadvertent movement of the guidewire during an interventional procedure can dislodge the filter.

The insertion of such known filters in the human vasculature which comprises very small diameter blood vessels may result in inappropriate haemodynamics which can exacerbate damage to the flowing blood and may result in haemolysis.

This invention is therefore directed towards providing an embolic protection device which will overcome these major problems.

Statements of Invention

According to the invention there is provided a vascular filtration device comprising:

a filter element operable to remove embolic material from blood when in use, the filter element having a plurality of openings disposed on at least a portion of the filter element;

wherein said openings are sized such that the shear stress imparted to blood moving through said filter element at physiological flow rates is less than about 800 Pa.

In a preferred embodiment of the invention the openings are generally circular openings.

Preferably the filter element comprises between 200 and 500 openings with an average diameter of between 50 and 200 microns.

Most preferably the filter element comprises at least 200 openings with an average diameter of no more than 200 microns.

Ideally the filter element comprises less than 500 openings with an average diameter of at least 50 microns.

In a particularly preferred embodiment the shear stress imparted to blood moving through said filter element at physiological flow rates is less than about 400 Pa. Most preferably the shear stress imparted to blood moving through said filter element at physiological flow rates is less than about 200 Pa.

Preferably the filter element comprises a collapsible filter body having a proximal inlet end and a distal outlet end, the proximal end of the filter body having one or more inlets to allow blood and embolic material to enter the filer body, the distal end of the filter body having the plurality of openings. Ideally, said filter body, when in a deployed configuration, includes a generally cylindrical intermediate section between said proximal and distal sections. Preferably the distal section of the filter body is generally tapered when in a deployed configuration. Ideally, said distal section of said filter body comprises at least a portion of the filter element. Preferably said intermediate section of said filter body comprises at least a portion of the filter element.

In a preferred embodiment the filter body includes a circumferential groove.

In one embodiment of the invention said filter body, when in a deployed configuration is defined by a generally elongated shape, having an intermediate section with an axial dimension and a transverse dimension, the ratio of the axial dimension to the transverse dimension being at least 0.5. Ideally, the ratio of the axial dimension to the transverse dimension is at least 1.0.

In one embodiment said filter element is formed from film material, especially a perforated film.

In another embodiment said filter element is formed from a mesh.

Preferably the number of outlet holes increases towards an outer edge of the distal end of the filter body.

In one aspect the invention provides a vascular filtration device comprising a collapsible filter body having a proximal inlet end and a distal outlet end, the proximal end of the filter body having one or more inlet openings to allow blood and embolic material to enter the filter body, the distal end of the filter body

having at least 200 outlet openings with an average diameter of less than 200 microns. Preferably the filter element comprises between 200 and 500 openings with an average diameter of between 50 and 200 microns. Ideally, the filter element comprises at least 200 openings with an average diameter of no more than 200 microns, most preferably the filter element comprises less than 500 openings with an average diameter of at least 50 microns.

In another aspect the invention the invention provides a vascular filtration device comprising:

a filter element operable to remove embolic material from blood when in use, the filter element having a plurality of openings disposed on at least a portion of the filter element;

wherein said plurality of openings is between 200 and 500 openings with an average diameter of between 100 and 200 microns; and

wherein said openings are sized such that the shear stress imparted to blood moving through said filter element at physiological flow rates is less than about 800 Pa.

Preferably the openings are generally circular.

Ideally the filter element comprises at least 200 openings with an average diameter of no more than 200 microns. Most preferably, the filter element comprises less than 500 openings with an average diameter of at least 100 microns.

In a further aspect the invention provides a vascular filtration device comprising:

a filter element operable to remove embolic material from blood when in use, the filter element having a surface and a plurality of openings disposed on at least a portion of the surface of the filter element;

the openings being distributed over the surface of the said filter element with a non-uniform density;

wherein said openings are sized such that the shear stress imparted to blood moving through said filter element at physiological flow rates is less than about 800 Pa.

In another aspect the invention provides a vascular filtration device comprising a collapsible filter body having a proximal inlet end, a distal outlet end and an intermediate section extending between the proximal portion and the distal portion, the proximal end of the filter body having one or more inlet openings to allow blood and embolic material to enter the filter body, the distal end of the filter body having a plurality of outlet openings, wherein in a deployed configuration the intermediate section is generally cylindrical with an axial dimension and a transverse dimension, the ratio of the axial dimension to the transverse dimension being at least 0.5. Ideally, said ratio is at least 1.0.

In a particularly preferred embodiment the filter body defines a three dimensional matrix.

Preferably the filter body is of a resilient elastomeric material.

The filter body may be of a polyurethane elastomer.

The filter body may be of a polycarbonate urethane material. The polycarbonate urethane may be prepared by reaction of an isocyanete, a chain extender and a polycarbonate copolymer polyol of alkyl carbonates.

In one embodiment of the invention the device includes:

a delivery system comprising a tubular member having a longitudinal axis, distal and proximal portions, said distal portion of the tubular member being removably advanceable into the vasculature of a patient;

a medical guidewire longitudinally axially movable in said tubular member and having distal and proximal portions;

the delivery system operably coupled to a filter body at least during delivery, the filter body having;

a first collapsed, insertion and withdrawal configuration and a second expanded, deployed configuration;

a proximal inlet section and a distal outlet section, said proximal inlet section including inlet openings which are operable to admit body fluid when the filter body is in the second expanded configuration;

a plurality of outlet openings disposed on at least a portion of the filter element adjacent to the distal outlet section;

wherein said filter body is moved between said first and second configurations by displacement of said delivery system.

The filter body preferably has a collapsible filter frame and a filter element operably coupled thereto.

Preferably said guidewire is solid.

Ideally said filter body comprises a sleeve slidably disposed on said guidewire.

The device preferably further comprises stops for limiting the range of longitudinal movement of the sleeve on said guidewire.

Ideally the sleeve further comprises a guide member distal to the filter body and tapering distally.

Preferably said frame comprises a plurality of support arms having proximal and distal ends.

Ideally the arms are formed of an elastic shape memory material.

Preferably said frame is constructed such that said filter body is biased toward said second, deployed configuration.

In a preferred arrangement said inlet openings are defined at least partially by said arms.

Ideally proximal portions of said arms extend generally outwardly and distally from said guidewire when said filter body is in said second, deployed configuration.

Preferably distal portions of said arms extend generally outwardly and proximally from said guidewire when said filter body is in said second, deployed configuration.

In one embodiment of the invention the distal portion of the tubular member further includes a pod for receiving therein the filter body when in said first, collapsed configuration.

Preferably said filter body is urged into said first, collapsed configuration by said pod when the guidewire is moved proximally.

Brief Description of Drawings

The invention will be more clearly understood from the following description thereof given by way of example only with reference to the accompanying drawings in which:-

Fig. 1 is a side view of an embolic protection device according to the invention, in use;

Fig. 2 is a side view of the device of Fig. 1 in a pre-loaded position for insertion;

Fig. 3A is a side view illustrating one method of fixing the device to catheter;

Fig. 3B is a side view of an embolic protection device incorporating the fixing of Fig. 3 A;

Fig. 4 is a side view illustrating another method of fixing;

Fig. 5 is an end view of a split collar used in the fixing of Fig 4;

Fig. 6 is a side view illustrating a further method of fixing;

Fig. 7 is an end view of a jubilee clip used in the fixing of Fig. 6;

Fig. 8 is a side view of one filter element used in the device of the invention;

Fig. 9 is a side view of another filter element;

Fig. 10 is a side view of the filter element of Fig 8 being removed;

Fig. 11 is an isometric view of another filter element in an in-use placed configuration;

Fig. 12 is a side view of the filter element of Fig. 11 in a retracted position for insertion and withdrawal;

Figs. 13 to 15 are side views of another filter element in different positions;

Figs. 16 and 17 are side views of part of a further filter element with a snap fit retrieval arrangement;

Fig. 18 is a perspective, partially cross-sectional view of another embolic protection device shown mounted in a vessel;

Figs. 19a to 19c are perspective views illustrating the formation of a collapsible filter support for use in the device of Fig. 18;

Figs. 20 to 22 are perspective views of other filter elements;

Fig. 23 is an elevational view of another filter element;

Fig. 24 is a sectional view taken along the line XXIV-XXIV of Fig. 23;

Fig. 25 is a sectional view taken along the line XXV-XXV of Fig. 23;

Fig. 26 is an enlarged detail view of portion of the filter;

Fig. 27 is an expanded view of the filter element of Fig. 23;

Fig. 28 is a side view illustrating one method in which the substrate tubing that the filter element is attached to can run over the primary crossing guidewire;

Fig. 29 is a side view illustrating the position in which the "olive" component will sit in order to provide a smooth transition between the primary crossing guidewire and the loading pod;

Fig. 30 is a perspective view of the filter element in its most distal position;

Fig. 31 is a perspective view of the filter element in its most proximal position;

Fig. 32 is a perspective view of the filter element when the distal end of the filter is not bonded to the substrate tubing;

Fig. 33 is a side view of a concertina shaped filter; A being when the filter is deployed and B when the filter is in its loaded shape;

Fig. 34 is a perspective view of the floating distal tip design with a spring element incorporated distal to the floating tip;

Fig. 35 is a side view of another floating distal tip design with a spring incorporated in the distal tip;

Fig. 36 is a side view of the floating distal tip design with the shape memory alloy extending from the proximal end to the distal end;

Fig. 37 is a perspective view of the mesh design incorporating a floating distal tip;

Fig. 38 illustrates perspective views of filter geometries;

Fig. 39 shows a fibrous mesh filter design with fibres woven at the distal end and converging into a number of bundles at the proximal end;

Fig. 40 is partially sectioned elevational view of an embolic protection device according to the invention;

Fig. 41 is a schematic sectional elevational view of the embolic protection device of Fig. 40;

Fig. 42 is a detail sectional view of portion of the device of Fig. 40;

Fig. 43 is a longitudinal cross sectional view of the device of Fig. 40;

Fig. 44 is a cross sectional view of a distal end of the device of Fig. 40;

Fig. 45 is a view on the line A-A in fig. 44;

Fig. 46 is a perspective view of a filter body of the device of Figs. 40 to 45;

Fig. 47 is a side elevation view of the filter body of Fig. 46;

Fig. 48 is a view on a proximal end of the filter body;

Fig. 49 is a developed view of the distal end of the filter body illustrating an arrangement of outlet holes;

Fig. 50 is a perspective view of a support frame;

Fig. 51 is a side elevational view of the support frame;

Fig. 52 is a perspective view illustrating the manufacture of the support frame;

Fig. 53 is a view of the support frame and filter element assembly; and

Fig. 54 is a side elevational view of another filter body of the invention.

Detailed Description

Referring to the drawings there are illustrated various embolic protection devices. The devices, in general, comprise a filter element for temporary placing in a desired position during a surgical or interventional procedure, typically using a guidewire and catheter. The filter element provides a pathway for blood and has means for capturing and retaining undesired embolic material released during the surgical procedure. The filter element containing the retained embolic material is removed when the interventional procedure is completed. In this way the patient is protected against the risk of stroke or other complications caused by the release of undesired embolic material during the procedure.

In one embodiment of the device it will be used in an over the wire transcatheter configuration. The clinician will cross the lesion with a steerable guidewire. The cerebral protection device will then be threaded over the guidewire and will be placed distal to the site of the lesion being treated. By means of actuation, or other means, the filter is deployed into the vessel and will capture emboli that are generated or dislodged during a balloon inflation and stent placement. The device consists of a filter attached to a shaft that can run over the primary crossing guidewire.

Referring initially to Figs. 1 and 2 in this case the filter element consists of a compressible porous structure polymeric foam filter element 1 overmoulded onto or joined to a polymeric or metallic tube or spring or other hollow support element 2. The foam filter element 1 is compressed into a housing or pod 3 at a distal end of the catheter 6 to advance it to the required location. Once in situ the housing 3 is withdrawn or the filter element 1 is advanced. This action allows the compressed filter element 1 to expand to the required size and occlude a blood vessel 4 except for the path or paths provided through the filter element 1. The filter element 1 is designed to provide a pathway or multiple pathways through for blood cells and other blood constituents but to capture emboli of a size greater than the filter pore size. Blood flow rate is maintained by forming the filter element such that a local pressure drop across the filter is minimised. The filter element 1 has proximal inlet end 7 and a distal outlet end 8. The inlet end 7 has a plurality of inlet openings sized to allow blood and embolic material enter the filter element. The outlet end 8 has a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the body of the filter element 1.

The filter element 1 in this case is of a porous structure or polymeric foam which has a open cell structure with a typical density less than 400 kg per cubic meter. Preferably the density will be less than 100 kg per cubic meter and ideally will be

less than 50 kg per cubic meter. The filter properties may be achieved through appropriately sizing the pores of the foam body or additionally by removing material to create appropriately sized pathways for blood to flow through and means of capturing larger sized particles. A number of configurations for this will be described that can tailor both the sizing and flow rate characteristics of the filter element 1 either independently or simultaneously. The actuation and deployment of the filter element 1 are achieved by providing relative motion between the filter element 1 and the covering housing 3.

It is not desirable that the catheter moves relative to the support element 2 during manipulation. Motion may be prevented by fixing the inner support element 2 to the catheter 6 in a number of different ways. In the embodiment described this is achieved by way of having a catheter 6 covering the support element 2 and filter element 1 to which it is fixed. As illustrated in Figs. 3A and 3B the fixing may be achieved by means of a shrink wrap tube 5 that is shrunk to capture both the covering catheter 6 and the inner support element 2. Once the filter element 1 is in the desired position, the shrink-wrap joint is broken using the peel-away tab 7 to allow the outer catheter 6 to be removed proximally and leave the support element 2 and filter element 1 in place.

A number of other workable arrangements could be used to join the support element 2 and catheter 6. A split collar arrangement 10 (Figs. 4 & 5) could be used that was removable by means of unlocking a screw or a number of screws or an arrangement such as a jubilee clip 11 (Figs. 6 & 7) which could be loosened to free the bond between the components.

Another method that could be used to temporarily fix the inner support element 2 to the outer sheath or catheter 6 is a Hemostatis High Pressure Touhy Borst Y adapter. This commercially available adapter is needed to enable the physician to flush the sheath before being inserted into the artery. The outer sheath or catheter may be permanently attached to this adapter. The inner tubular supper element 2

runs through the Touhy Borst section of the adapter and thus through the centre of the sheath. Tightening the Touhy Borst section releases this grip, thus allowing the inner tubular support element 2 and the outer sheath to move relative to each other once again.

The design of the filter element 1 is shown in a typical embodiment in Fig. 8, where a foam substrate filter body has material removed to create a series of channels or pathways 20 for the blood to flow through but which would cause a restriction for embolic material to prevent it going through the filter. The pathways 20 may be machined using a variety of methods such as laser cutting with excimer, UAG, CO2, or other laser type, freezing and machining or lost wax machining. A number of arrangements are possible with the sizing reflective of the requirements. In the configuration shown, the inlet holes are preferably 0.5 mm or greater in size to capture large emboli while the outlet holes are less than 300 microns. These can be easily varied as required to filter differing sized particles from a variety of fluid media in a variety of vessel sizes.

The filter media can be bonded to the tubing substrate by way of a variety of available technologies such as mechanical, solvent or adhesive bonding and overmoulding in an arrangement such that the substrate is placed in the mould and the polymer material is then shot into the mould and forms a bond at the interface between the substrate and the polymer element. Additionally, the foam or porous element could be extruded onto or bonded to a substrate.

It will be noted that the filter element 1 has a rounded distal end 21 to facilitate insertion and the proximal end 22 is tapered to facilitate withdrawal. Alternatively, as illustrated in Fig. 9 the distal end 23 may be tapered.

Referring particularly to Fig. 10 at the end of the interventional procedure, the device can be withdrawn by means of advancing a large open catheter 25 to the proximal end 22 of the filter 1 and pulling the filter 1 into the catheter 25. The

filter 1 will compress and seal the proximal filter inlet openings after the initial taper is drawn into the catheter 25 before collapsing the rest of the filter body. Once the filter 1 has been withdrawn fully into the catheter 25 it can then be readily removed from the patient. The filter 1 will contain the captured emboli.

In another embodiment of the invention as illustrated in Figs. 11 to 15, an arrangement of spokes 30 covered with a membrane or porous fabric or mesh 31 can be folded down into a delivery sheath or pod for subsequent deployment in the target vessel. The design consists of a substrate shaft 33 onto which are radially or circumferentially bonded a series of pre-shaped wires 30. The wires 30 are joined on the proximal end into a movable collar or tube 32 mounted on the substrate shaft 33 and at the distal end into a fixed tube 34. The tube 32 can move proximally and distally to the extent that it will open and close the assembly in a manner similar to an umbrella and thereby occlude the vessel. The spokes 30 may be fabricated in a range of metallic, polymeric and composite materials. The frame is covered with a porous material 31, whose pore size is selected to allow the media through, effectively creating a screen filter. The covering fabric 31 could be bonded to the frame 30 by means of casting a material such as polyurethane or PET onto the pre-formed shape. The film may then be lazed or made porous by other means such as mechanical or heat punching or by chemical etching. Additionally, incorporating a soluble particle in the polymer matrix, subsequent removal of the particle would render the polymer porous. Control of porosity is achieved by tailoring the ratio and distribution of the particulate within the polymer matrix.

When the assembly is configured longitudinally a sheath or pod may be slid over it to cover it. As with the previous embodiment, the loaded catheter is positioned in the required location by threading it over the guidewire. Once the desired location has been reached, the sheath may be moved back and allow the assembly be exposed in the vessel. A sleeve 35 can then be moved forward to open or deploy the assembly. The relative sizing and choice of materials operates such

that the sleeve 35 will not slide on the inner tubing unless an external force is applied to move it. When deployed, the device will remain open and catch whatever embolic material is moving towards the brain. At the end of the procedure, a pre-shaped component advanced over the inner tube will dock with the movable tube 32 and allow it to be slid towards the proximal end of the device with the result that the structure is closed. A larger sheath can then separately be advanced to the site of the filter and the filter may be pulled or manipulated proximally into it. When withdrawn into the sheath or catheter, the device may then be removed either over the guidewire or with it.

Referring to Figs. 16 to 17 there is illustrated another embolic protection device. In this case the filter element has a design based on a shaped thin film component bonded onto the tubing substrate. A wide number of shapes could be made to work in the application. An element which through its pre-shaped form will open into a framework 40 when the restraining force is removed is attached to a tubing substrate 51. The frame element 40 can be manufactured from a range of metallic or polymeric components such as a shape memory alloy like Nitinol or a shape memory polymer or a shaped stainless steel or metal with similar properties that will recover from deformation sufficiently to cause the film component to open. Otherwise a mechanical movement or actuation can cause the device to open. The shaped film component is attached over the frame 40. The film component can be formed by a number of known commercial technologies. These include blow-moulding, dip casting, solution casting, spin casting and film welding as well as adhesive joining. The object is to produce a formed shape that can be opened in the vessel to a size and shape to occlude it. Filtration is achieved by creating a pattern or series of openings in the proximal and distal ends of the element that allows emboli and blood to enter the device but having a range of smaller openings in the distal end to allow the blood to pass through to the distal vasculature while retaining the emboli.

While being delivered to the required site, the filter element is covered or restrained by a sheath. By withdrawing the sheath or advancing the filter device, the filter is uncovered and opens to occlude the vessel. During the procedure, the filter acts to capture all embolic material that attempts to flow distally. At the end of the procedure, a sheath is advanced to the proximal end of the device and the filter is pulled proximally into it with the retained emboli captured. In this design configuration, the emboli can easily be removed for analysis afterwards.

The invention above is described as it relates to a device that can be used over a medical guidewire. The opportunity exists to configure the invention in a manner that it could in itself be used as the primary crossing device. All of the filter designs described above could be mounted onto either the over the wire or the primary crossing device as described hereunder. For a primary crossing device the filter would be bonded to a solid substrate. Some benefits would accrue in that the inner diameter onto which the filter could be wrapped down would be smaller because it would not need to move over another instrument. Fig. 18 illustrates the differences involved. The filter element 1 is mounted on the substrate shaft 33. A collapsible filter support element 50 is mounted on the substrate shaft 33 at a proximal end of the filter 1. The support element 50 has a number of foldable arms 51 which collapse against the shaft 33 for deployment and upon release extend outwardly to expand the filter 1 in the vessel.

Referring to Figs. 20 to 22 there is shown alternative constructions of filter element comprising a compressible filter 1 shown in an expanded position with a large inlet opening 60 and smaller outlet openings 61. A collapsible wire support 62 is provided at a proximal end of the filter 1. The wire support 62 is collapsible with the filter 1 within a housing or pod for deployment and upon release expands to support the filter 1 in the vessel 4.

An alternative filter arrangement is shown in Figs. 23 to 27. In this case, the filter comprises a Nitinol mesh which is expandable from a collapsed position shown in

Fig. 23 for deployment to an expanded in use position shown in Fig. 27 to provide a filter body 65 with proximal inlet 66 and distal outlets 67.

For a primary crossing device, the distal end of the device will be flexible and atraumatic. This can be achieved by a number of means such as fabricating a spring or polymeric element to be flexible enough to deflect when it comes into contact with the walls of the vessel. The tip section would be mounted distally to the filter element. An intermediate section of the device will house the filter 1 which would be covered prior to deployment. A sheath could be fully the length of the device or attached by an actuator to a shorter sheath that covers the filter only. The proximal section of the device will provide a platform for the balloon dilation and stent devices. The provision of a platform may be achieved as shown by removing the proximal covering to expose a wire or spring assembly. Alternatively, the whole proximal section could function as the platform. Essentially, to function as the platform for balloon catheter and stent, the devices should be sized with an outside diameter dimension that allows free movement of the catheter systems over it. Typical industry standards for coronary products permit free movement of devices over a 0.014" or 0.018" diameter while peripheral angioplasty applications use a 0.035" OD.

Referring to Fig. 28 the tubing substrate 33 onto which the filter element is bonded can move between two stoppers 63 and 64, the stoppers are mounted on the primary crossing guidewire 2. The stoppers can be manufactured from a range of metallic or polymeric components, which will permit movement of the tubing substrate 33 between them. The stoppers may also be in the form of a step in the actual medical guidewire. A large variation in distances between stoppers 63 and 64 could be made to work in this application. The stoppers are sized to prevent movement of the tubing substrate either over or under them so that they act as a stop position for the tubing substrate in both their proximal and distal locations. The stoppers can be mounted onto the primary crossing guidewire by a number of known commercial technologies; these include soldering, welding, braising,

crimping and adhesive bonding. The proximal stopper will be small enough in size to fit into the internal shaft of the delivery catheter. The filter element can move axially and rotationally independently of the guidewire. This allows for good wire movement and control of filter position. The filter position will be maintained during the exchange of catheters. Any commercially known available guidewire can be adapted accordingly and used with this technique.

Fig. 29 refers to an "olive" 65; the olive component can be manufactured from a range of metallic or polymeric components such as polymeric foams, plastics, stainless steel or metal. The olive will allow a smooth transition between the guidewire 2 and the pod 3 into which the filter element is loaded and also allows for easy positioning of the filter element within the pod. The olive can be directly attached to the guidewire or it may also be attached to a tubing substrate 33. The olive can be attached to the guidewire or tubing substrate by a range of known techniques such as adhesive bonding and soldering. The olive will work as required for a range of distances distal to the filter element. A wide number of shapes and sizes could be made to work as the olive component.

Fig. 30 refers to the filter element 1 when it is positioned in its most distal position. The filter element may achieve this position during loading or after deployment. The stopper element 64 prevents the filter element 1 from moving beyond it in the distal direction.

Fig. 31 illustrates the filter element in its most proximal location the filter element may achieve this position when deploying the device or after deployment. The stopper element 63 prevents the filer element 1 from moving beyond it in the proximal direction.

Fig. 32 refers to a floating distal tip in this case a stopper component 66 is placed proximal to the distal end of the filter. The most distal end of the filter being fixed to a marker bond 70 or other suitable substrate. The marker bond 70 is not fixed

to the substrate tubing 33. This allows the distal end of the filter freedom of movement in the axial direction beyond the stopper component. The stopper component can be made to work using any shape or form so as to prevent movement of the distal end of the filter in the proximal direction beyond the point of fixturing of the stopper component. The stopper component may be manufactured from metals or polymeric material, it can be joined to the tubing substrate 33 by a number of existing technologies including adhesive bonding and soldering. The stopper component 66 will work when placed in any location between 50 and 70. A floating distal tip on the filter element will facilitate the loading of the filter element into the loading pod as the filter can now extend in the axial direction and therefore be wrapped down over a greater length. This will reduce the loading force required and also reduce the profile of the loaded filter. The floating distal tip design will facilitate the loading of a large range of filter designs.

Fig. 33 refers to a concertina shaped filter with a floating distal tip. This filter geometry adds to the circumferential integrity of the filter and thus prevents the formation of creases along the length of the filter. "A" illustrates the filter as it will be when in position. "B" illustrates how the distal tip will extend in the axial direction when the filter element is loaded into a loading pod. The floating tip design can be used to accommodate the loading of many filter shape designs. For the filter design shown a longer pod is needed to accommodate the increase in axial length of the filter element when loaded.

Fig. 34 refers to the floating distal tip design with a spring element 67 incorporated into the design. The spring is placed distal to the filter element. As previously illustrated in Fig. 33, the floating distal tip extends in the axial direction when loaded, the spring acts as a safety device when the filter is deployed and ensures the return of the floating distal tip to its primary location. The spring element will be soft enough to allow the distal tip to extend freely in the distal direction during loading but stiff enough to push the distal tip back to its primary location after

deployment. The spring element can be manufactured from either a polymeric or metal component. The spring element can be mounted onto a substrate 33 and a stopper component used to prevent axial movement of the spring in the distal direction. Other methods of keeping the distal end of the spring element stationary could be used such as bonding, welding, crimping, soldering or crimping the distal end of the spring onto the substrate 33. This technique could also be made to work with the spring being part of the actual guidewire. There are many other configurations by which a return spring element may be incorporated into the filter as shown in Fig. 35 and 36.

In Fig. 35 the spring element 67 is bonded to the substrate 33 at its proximal end and the distal end of the filter element is bonded to the spring shaft. This design allows the distal end of the filter element to extend in the distal direction. The extension length could be determined by either the positioning of a stopper 68 or the stiffness of the spring. When external forces are removed from the filter the spring will return the filter to its primary location. In Fig. 36 a shape memory alloy such as nitinol is used to return the filter to its primary location. The nitinol support frame 69 is fixed to the substrate 33 at its proximal end 70 and is floating at the distal end 71. The shape memory properties of the nitinol will ensure that the filter element returns to its primary location. This design can facilitate the use of any other commercially available or known shape memory alloys. This design could also be made to work using a spring component.

Fig. 37 again incorporates the floating distal tip design. The filter body 65 as previously illustrated in Fig. 27 is mounted onto a substrate 33. At the proximal end the stent is fixed to the substrate. The floating distal tip design allows the filter body 65 to extend in the distal direction. As the filter body 65 extends there is a reduction in its outside diameter and an increase in it overall length. There may or may not be need for a stopper 68 as the filter body 65 will extend up to its own elastic limit which is determined by its size and geometry. The shape memory function of the filter body 65 will cause the distal tip to return to its

primary location when external forces are removed from it. The proximal end of the filter body 65 may be fixed to the substrate by a number of known technologies such as bonding, soldering or crimping.

Fig. 38 illustrates a number of different filter designs which could be made to work as embolic protection devices. These filter designs all work to reduce the longitudinal length of creases which may occur should the filter be oversized, therefore acting as crease breakers. Either ends of the filters shown could act as both proximal and distal ends for the filter. The filter body may be tubular or frusto-conical.

Referring to Figs. 40 to 42 there is illustrated an embolic protection device according to the invention indicated generally by the reference number 100. The device 100 has a guidewire 101 with a proximal end 102 and a distal end 103. A tubular sleeve 104 is slidably mounted on the guidewire 101. A collapsible filter 105 is mounted on the sleeve 104, the filter 105 being movable between a collapsed stored position against the sleeve 104 and an expanded position as shown in the drawings extended outwardly of the sleeve 104 for deployment in a blood vessel.

The sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101.

The filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111. The mesh net 110 is gathered in the sleeve 104 at each end; the net 110 being rigidly attached to a proximal end 112 of the sleeve 104 and the net 110 being attached to a collar 115 which is slidable along a distal end 114 of the sleeve 104. Thus the distal end of the net 110 is longitudinally slidable along the sleeve 104. The support frame 111 is also fixed at the proximal end 112 of the sleeve 104. A distal end 116 of the support frame 111 is not attached to the sleeve 104 and is

thus also free to move longitudinally along the sleeve 104 to facilitate collapsing the support frame 111 against the sleeve 104. The support frame 111 is such that it is naturally expanded as shown in the drawings and can be collapsed inwardly against the sleeve 104 for loading in a catheter 118 or the like.

The filter 105 has large proximal inlet openings 117 and small distal outlet openings 119. The proximal inlet openings 117 allow blood and embolic material to enter the filter body, however, the distal outlet openings 119 allow through passage of blood but retain undesired embolic material within the filter body.

An olive guide 120 is mounted at a distal end of the sleeve 104 and has a cylindrical central portion 121 with tapered ends 122, 123. The distal end 122 may be an arrowhead configuration for smooth transition between the catheter and olives surfaces. The support frame 111 is shaped to provide a circumferential groove 125 in the filter net 110. If the filter is too large for a vessel, the net may crease and this groove 125 ensures any crease does not propagate along the filter.

Enlarged openings are provided at a proximal end of the filter net 110 to allow ingress of blood and embolic material into an interior of the net 110.

In use, the filter 105 is mounted in a collapsed state within a distal end of the catheter 118 and delivered to a deployment site. When the filter is correctly positioned the catheter 118 is retracted allowing the support frame 111 to expand inflating the net 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the net 110. The blood will pass through the net wall, however, the openings or pores in the net are sized so as to retain the embolic material. After use the catheter is delivered along the guidewire 101 and slid over the filter 105 engaging the proximal inlet 112 first to close the openings and then gradually collapsing the net against the sleeve 104 as the catheter 118 advances over the filter 105. Once the filter 105 is fully loaded in the catheter 118, it can then be withdrawn.

It will be noted that a proximal end of the filter is fixed and a distal end of the filter is longitudinally movable along the sleeve to facilitate collapsing of the filter net.

Further, the catheter engages the proximal end of the filter net first thus closing the filter net inlet and preventing escape of embolic material from the filter net as the filter net is being collapsed.

The outer filter body 110 is preferably of a resilient biocompatible elastomeric material. The material may be a polyurethane based material. There are a series of commercially available polyurethane materials that may be suitable. These are typically based on polyether or polycarbonate or silicone macroglycols together with a diiocyanate and a diol or diamine or alkanolamine or water chain extender. Examples of these are described in EP-A-461,375 and US 5,621,065. In addition, polyurethane elastomers manufactured from polycarbonate polyols as described in US 5,254,622 (Szycher) are also available.

The filter body may also be a biostable polycarbonate urethane article an example of which may be prepared by reaction of an isocyanate, a chain extender and a polycarbonate copolymer polyol or alkyl carbonates. This material is described in our co-pending PCT Application No. IE98/00091, filed November 9, 1998, the entire contents of which are incorporated herein by reference.

The filter body may be manufactured from a block and cut into a desired shape. However the filter is preferably formed by dipping a rod of desired geometry into a solution of the material which coats the rod. The rod is then dissolved. The final geometry of the filter may be determined in the dipping step or the final geometry of the filter may be determined in the dipping step or the final geometry may be achieved in a finishing operation. Typically the finishing operations

involve processes such as mechanical machining operations, laser machining or chemical machining.

The filter body is of hollow construction and is formed as described above by dipping a rod in a solution of polymeric material to coat the rod. The rod is then dissolved, leaving a hollow body of polymeric material. The rod may be of an acrylic material which is dissolved by a suitable solvent such as acetone.

The polymeric body thus formed is machined to the shape illustrated in Figs. 40 to 53. The final machined filter body comprises an inlet or proximal portion 210 with a proximal neck 212, an outlet or distal portion 213 with a distal neck 214, and an intermediate portion 215 between the proximal and distal portions.

The inlet holes 117 are provided in the proximal portion 210 which allow both blood and embolic material to flow into the filter body. In this case the proximal portion 210 is of generally conical shape to maximise the hole size.

The outlet holes 119 are provided in the distal portion 213 which allow blood to pass and retain embolic material in the filter body.

We have found that the optimum average diameter of the outlet holes is from 100 to 200 microns, ideally approximately 150 microns. The number of holes in the distal portion 213 is from 200 to 500, ideally about 300. This hole size and number of holes minimises shear levels by reducing localised flow rates. Thus, we have found that shear can be maintained below 800, preferably below 500 and ideally below 200 Pa at a blood flow rate of up to 270 ml/min in a 4 mm blood vessel.

We have found that by maintaining blood shear below 800, preferably below 500 and ideally below 200 Pa, the filter provides appropriate haemodynamics to minimise turbulence and inappropriate shear stress on native arteries and veins.

Damage to flowing blood such as haemolysis which involves the destruction of red blood cells by rupture of the cell envelope and release of contained haemoglobin is avoided. The outlet hole size and number of holes is optimised in order to capture embolic material, to allow the embolic material to be entrapped in the filter body and to be withdrawn through a delivery device such as a delivery catheter on collapsing of the filter body.

Shearing of red blood and damage platelets during filtration is a problem easily solved in extra-corporeal circuits by providing large filter areas with consequent low flow rates through individual pores controlled to flow rates such that the shear is maintained in ranges that are below known threshold levels with clinical relevance.

However, as shear stress increases in inverse proportion to the cube of the radius, small blood vessels do not provide space in which to control shear levels by reducing localised flow rates. At flow rates up to 270 ml/min in a 4mm blood vessel we have found that we can maintain shear at levels below 200 Pa with 150 micron holes.

The generally conical shape of the distal portion 213 facilitates the provision of a relatively large number of outlet holes without adversely affecting the structural properties of the filter body. However, several other geometrics are possible such as a double cone 250, 251 and intervening cylinder 252. Such a filter body 23 is illustrated in Fig. 54. This geometry facilitates the provision of an even greater number of outlet holes.

The intermediate portion 215 is also hollow and in this case is of generally cylindrical construction. This is important in ensuring more than simple line contact with the surrounding blood vessel. The cylindrical structure allows the filter body to come into soft contact with the blood vessel to avoid damaging the vessel wall.

The intermediate portion 215 is provided with a radial stiffening means, in this case in the form of a radial strengthening ring or rim 220. The ring 220 provides localised stiffening of the filter body without stiffening the material in contact with the vessel. Such an arrangement provides appropriate structural strength so that circumferential apposition of the filter body to the vessel wall is achieved. It is expected that other geometrics of stiffening means will achieve a similar result.

The tubular intermediate portion 215 is also important in maintaining the stability of the filter body in situ to retain captured emboli and to ensure that flow around the filter is minimised. For optimum stability we have found that the ratio of the length of the intermediate portion 215 of the filter body to the diameter of the intermediate portion 216 is preferably at least 0.5 and ideally greater than 1.0.

The collapsible support frame 111 has four foldable arms 290 which are collapsed for deployment and upon release extend outwardly to expand the filter body 110.

The support frame 111 can be manufactured from a range of metallic or polymeric components such as a shape memory alloy like nitinol or a shape memory polymer or a shaped stainless steel or metal with similar properties that will recover from the deformation sufficiently to cause the filter body 110 to open.

The support frame may be formed as illustrated in Fig. 52 by machining slots in a tube 291 of shape memory alloy such as nitinol. On machining, the unslotted distal end of the tube filter forms a distal collar 293 and the unslotted proximal end of the tube forms a proximal collar 294. In use, as described above, the distal collar 293 is slidably movable along the tubular sleeve 104 which in turn is slidably mounted on the guidewire 101 for deployment and retrieval. The proximal collar 294 is fixed relative to the tubular sleeve 104.

To load the filter the sub assembly of the support frame and filter body is pulled back into the catheter 118 to engage the distal stop 107. The support arms 290 are hinged inwardly and the distal collar 293 moves forward along the tubular sleeve 104. As the support arms 290 enter the catheter 118 the filter body 110 stretches as the filter body collar 115 slides along the tubular sleeve 104 proximal to the olive 120. On deployment, the catheter 118 is retracted proximally along the guidewire 101 initially bringing the collapsed filter assembly with it until it engages the proximal stop 106. The catheter sleeve then begins to pull off the filter freeing the support arms 290 to expand and the filter body apposes the vessel wall.

For retrieval, a retrieval catheter is introduced by sliding it over the guidewire 101 until it is positioned at the proximal end of the filter body and support frame. Pulling the guidewire 101 will initially engage the distal stop 107 with the filter element and begin to pull it into the retrieval catheter. The initial travel into the delivery catheter acts to close the proximal openings of the filter element, thus entrapping the embolic load. As the filter continues to be pulled back the filter body and the support frame are enveloped in the retrieval catheter. The collapsed filter may then be removed from the patient.

Conveniently the tip of the catheter which forms a housing or pod for reception of the filter is of an elastic material which can radially expand to accommodate the filter with the captured embolic material. By correct choice of material, the same catheter or pod can be used to deploy and retrieve the filter. For deployment, the elastic material holds the filter in a tightly collapsed position to minimise the size of the catheter tip or pod. Then, when retrieving the filter, the catheter tip or pod is sufficiently elastic to accommodate the extra bulk of the filter due to the embolic material.

Also, the filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example, during exchange of medical devices or when changing catheters.

It will also be noted that the filter according to the invention does not have a sharp outer edge as with many umbrella type filters. Rather, the generally tubular filter shape is more accommodating of the interior walls of blood vessels.

Conveniently also when the filter has been deployed in a blood vessel, the catheter can be removed leaving a bare guidewire proximal to the filter for use with known devices such as balloon catheter and stent devices upstream of the filter.

Claims

1. A vascular filtration device comprising:

a filter element operable to remove embolic material from blood when in use, the filter element having a plurality of openings disposed on at least a portion of the filter element;

wherein said openings are sized such that the shear stress imparted to blood moving through said filter element at physiological flow rates is less than about 800 Pa.

2. A device as claimed in claim 1 wherein the openings are generally circular openings.

3. The device of claim 1 or 2 wherein the filter element comprises between 200 and 500 openings with an average diameter of between 50 and 200 microns.

4. The device of any of claims 1 to 3 wherein the filter element comprises at least 200 openings with an average diameter of no more than 200 microns.

5. The device of any of claims 1 to 4 wherein the filter element comprises less than 500 openings with an average diameter of at least 50 microns.

6. The device of any of claims 1 to 5 wherein the shear stress imparted to blood moving through said filter element at physiological flow rates is less than about 400 Pa.

7. The device of any of claims 1 to 6 wherein the shear stress imparted to blood moving through said filter element at physiological flow rates is less than about 200 Pa.

8. The device as claimed in any preceding claim wherein the filter element comprises a collapsible filter body having a proximal inlet end and a distal outlet end, the proximal end of the filter body having one or more inlets to allow blood and embolic material to enter the filer body, the distal end of the filter body having the plurality of openings.

9. The device of claim 8, wherein said filter body, when in a deployed configuration, includes a generally cylindrical intermediate section between said proximal and distal sections.

10. The device of claim 9, wherein the distal section of the filter body is generally tapered when in a deployed configuration.

11. The device of claim 10, wherein said distal section of said filter body comprises at least a portion of the filter element.

12. The device of claim 9 wherein said intermediate section of said filter body comprises at least a portion of the filter element.

13. The device of any of claims 9 to 12 wherein said filter body includes a circumferential groove.

14. The device in any of claims 1 to 13, wherein said filter body, when in a deployed configuration is defined by a generally elongated shape, having an intermediate section with an axial dimension and a transverse dimension, the ratio of the axial dimension to the transverse dimension being at least 0.5.

15. The device of claim 15 wherein the ratio of the axial dimension to the transverse dimension is at least 1.0.

16. The device of claim 1, wherein said filter element is formed from film material.

17. The device of claim 1, wherein said filter element is formed from a mesh.

18. The device as claimed in any of claims 8 to 17 wherein the number of outlet holes increases towards an outer edge of the distal end of the filter body.

19. A vascular filtration device comprising a collapsible filter body having a proximal inlet end and a distal outlet end, the proximal end of the filter body having one or more inlet openings to allow blood and embolic material to enter the filter body, the distal end of the filter body having at least 200 outlet openings with an average diameter of less than 200 microns.

20. The device of claim 19 wherein the filter element comprises between 200 and 500 openings with an average diameter of between 50 and 200 microns.

21. The device of claims 19 or 20 wherein the filter element comprises at least 200 openings with an average diameter of no more than 200 microns.

22. The device of any of claims 19 to 21 wherein the filter element comprises less than 500 openings with an average diameter of at least 50 microns.

23. A vascular filtration device comprising:

a filter element operable to remove embolic material from blood when in use, the filter element having a plurality of openings disposed on at least a portion of the filter element;

wherein said plurality of openings is between 200 and 500 openings with an average diameter of between 100 and 200 microns; and

wherein said openings are sized such that the shear stress imparted to blood moving through said filter element at physiological flow rates is less than about 800 Pa.

24. The device of claim 23, wherein the openings are generally circular.

25. The device of claim 23, wherein the filter element comprises at least 200 openings with an average diameter of no more than 200 microns.

26. The device of claim 23, wherein the filter element comprises less than 500 openings with an average diameter of at least 100 microns.

27. A vascular filtration device comprising:

a filter element operable to remove embolic material from blood when in use, the filter element having a surface and a plurality of openings disposed on at least a portion of the surface of the filter element;

the openings being distributed over the surface of the said filter element with a non-uniform density;

wherein said openings are sized such that the shear stress imparted to blood moving through said filter element at physiological flow rates is less than about 800 Pa.

28. A vascular filtration device comprising a collapsible filter body having a proximal inlet end, a distal outlet end and an intermediate section extending between the proximal portion and the distal portion, the proximal end of the filter body having one or more inlet openings to allow blood and embolic material to enter the filter body, the distal end of the filter body having a plurality of outlet openings, wherein in a deployed configuration the intermediate section is generally cylindrical with an axial dimension and a transverse dimension, the ratio of the axial dimension to the transverse dimension being at least 0.5.

29. The device as claimed in claim 21 wherein said ratio is at least 1.0.

30. The device as claimed in any preceding claim wherein the filter body defines a three dimensional matrix.

31. The device as claimed in any preceding claim wherein the filter body is of a resilient elastomeric material.

32. The device as claimed in any preceding claim wherein the filter body is of a polyurethane elastomer.

33. The device as claimed in any preceding claim wherein the filter body is of a polycarbonate urethane material.

34. The device as claimed in claim 33 wherein the polycarbonate urethane is prepared by reaction of an isocyanete, a chain extender and a polycarbonate copolymer polyol of alkyl carbonates.

35. The device as claimed in any preceding claim including:

a delivery system comprising

a tubular member having a longitudinal axis, distal and proximal portions, said distal portion of the tubular member being removably advanceable into the vasculature of a patient;

a medical guidewire longitudinally axially movable in said tubular member and having distal and proximal portions;

the delivery system operably coupled to a filter body at least during delivery, the filter body having;

a first collapsed, insertion and withdrawal configuration and a second expanded, deployed configuration;

a proximal inlet section and a distal outlet section, said proximal inlet section including inlet openings which are operable to admit body fluid when the filter body is in the second expanded configuration;

a plurality of outlet openings disposed on at least a portion of the filter element adjacent to the distal outlet section;

wherein said filter body is moved between said first and second configurations by displacement of said delivery system.

36. The device of claim 35 wherein the filter wherein the filter body has a collapsible filter frame and a filter element operably coupled thereto.

37. The device of claim 35 or 36 wherein said guidewire is solid.

38. The device of claim 35 wherein said filter body comprises a sleeve slidably disposed on said guidewire.

39. The device of claim 38 further comprising stops for limiting the range of longitudinal movement of the sleeve on said guidewire.

40. The device of claim 39 wherein the sleeve further comprises a guide member distal to the filter body and tapering distally.

41. The device of any of claims 36 to 40 wherein said frame comprises a plurality of support arms having proximal and distal ends.

42. The device of claim 41 wherein the arms are formed of an elastic shape memory material.

43. The device of claim 41 or 42 wherein said frame is constructed such that said filter body is biased toward said second, deployed configuration.

44. The device of any of claims 41 to 43 wherein said inlet openings are defined at least partially by said arms.

45. The device of any of claims 41 to 44 wherein proximal portions of said arms extend generally outwardly and distally from said guidewire when said filter body is in said second, deployed configuration.

46. The device of any of claims 41 to 45 wherein distal portions of said arms extend generally outwardly and proximally from said guidewire when said filter body is in said second, deployed configuration.

47. The device of any of claims 35 to 46 wherein the distal portion of the tubular member further includes a pod for receiving therein the filter body when in said first, collapsed configuration

48. The device of claim 47 wherein said filter body is urged into said first, collapsed configuration by said pod when the guidewire is moved proximally.

Abstract

"An embolic protection device"

An embolic protection device has a collapsible filter element (105) mounted on a carrier such as a guidewire (101). The filter element (105) collapses into the outer end of a catheter (118) for deployment and retrieval through a vascular system of a patient. The filter element (105) has a collapsible filter body with a proximal inlet end and a distal outlet end. The proximal inlet end has inlet openings sized to allow blood and embolic material enter the filter body. The outlet end has outlet openings which allow through passage of blood but retain embolic material within the filter body. After use, the catheter (118) is movable along the guidewire (101) to engage the proximal end of the filter element and close the inlet openings before sliding over the filter element from the proximal end to the distal end to progressively collapse the filter body of the guidewire(101) for retrieval. The filter element (105) may conveniently be mounted on a tubular sleeve (104) which is slidable and rotatable on the guidewire (101) between spaced-apart stops (106, 120) on the guidewire (101) which allows some manipulation of the guidewire independently of the filter when the filter is in use. The filter element comprises between 200 and 500 outlet openings with an average dimension of between 50 and 200 microns. The openings are sized such that the shear stress imparted to blood moving through said filter element at physiological flow rates less than about 800 Pa.

Fig. 2

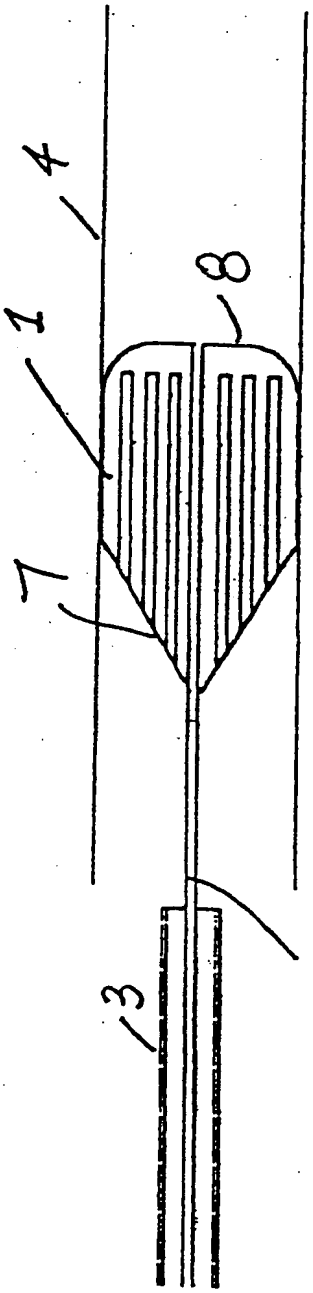


Fig. 1

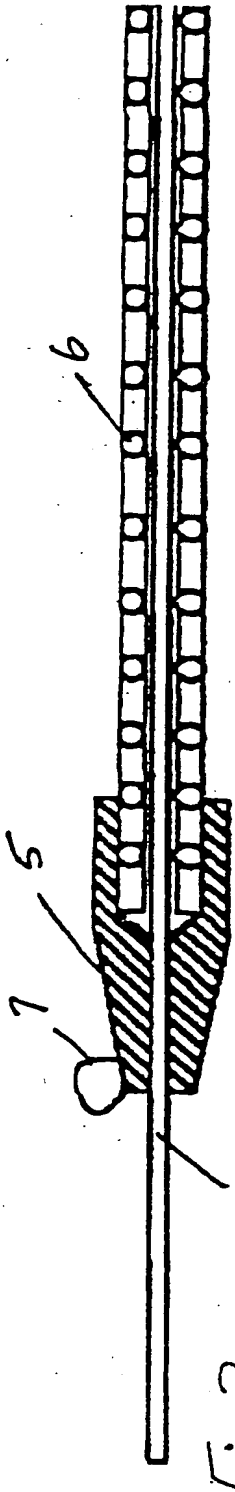


Fig 3a

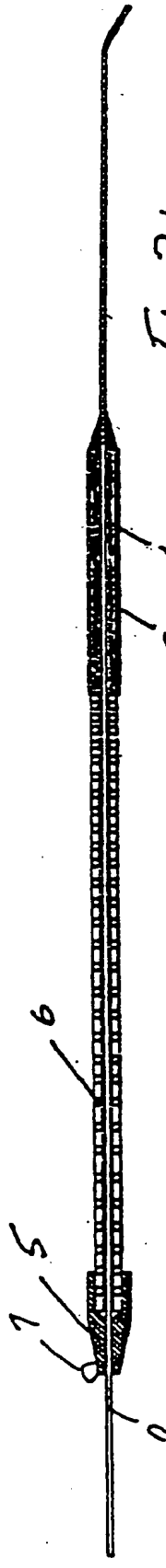


Fig 3b

Fig 5

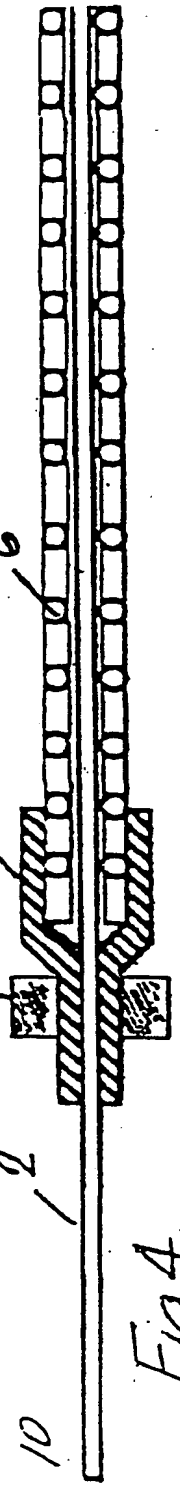


Fig 4

Fig. 6

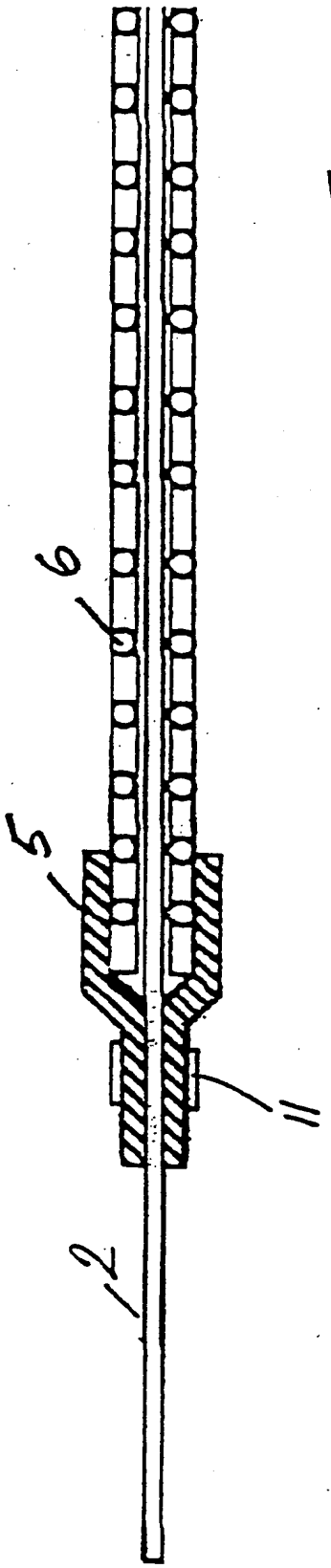
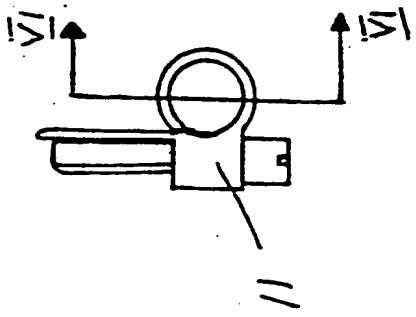


Fig. 7



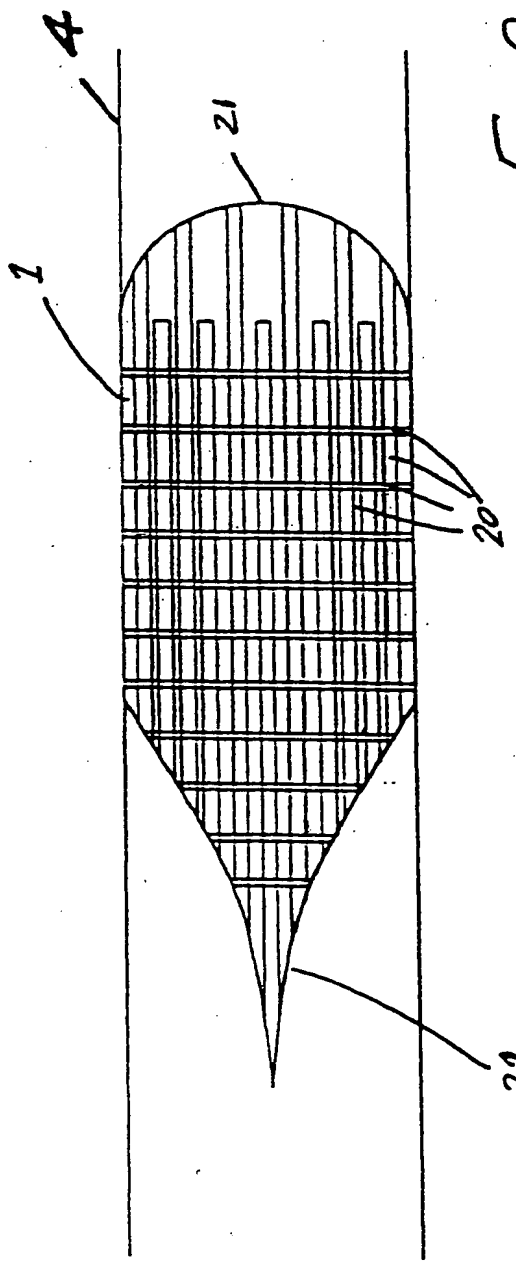


Fig. 8

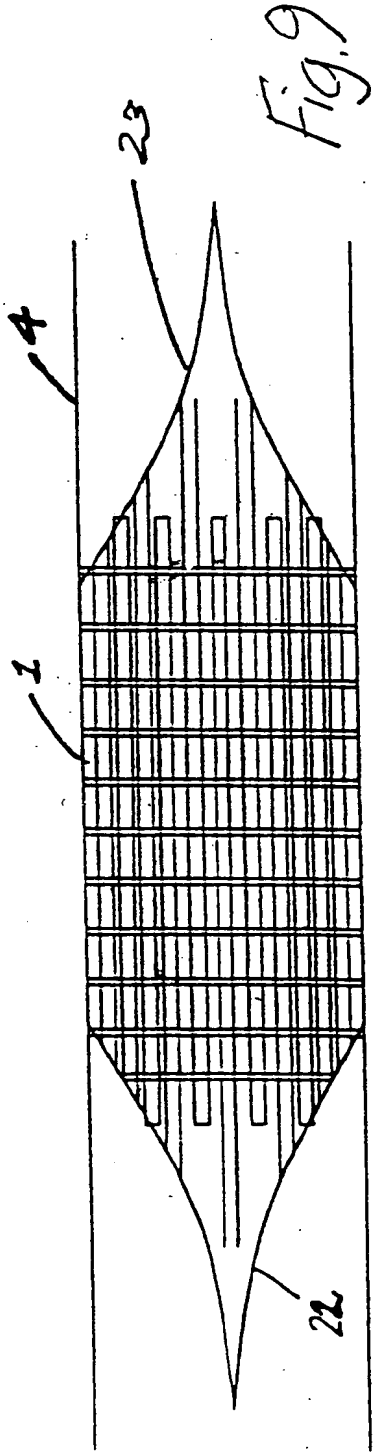


Fig. 9

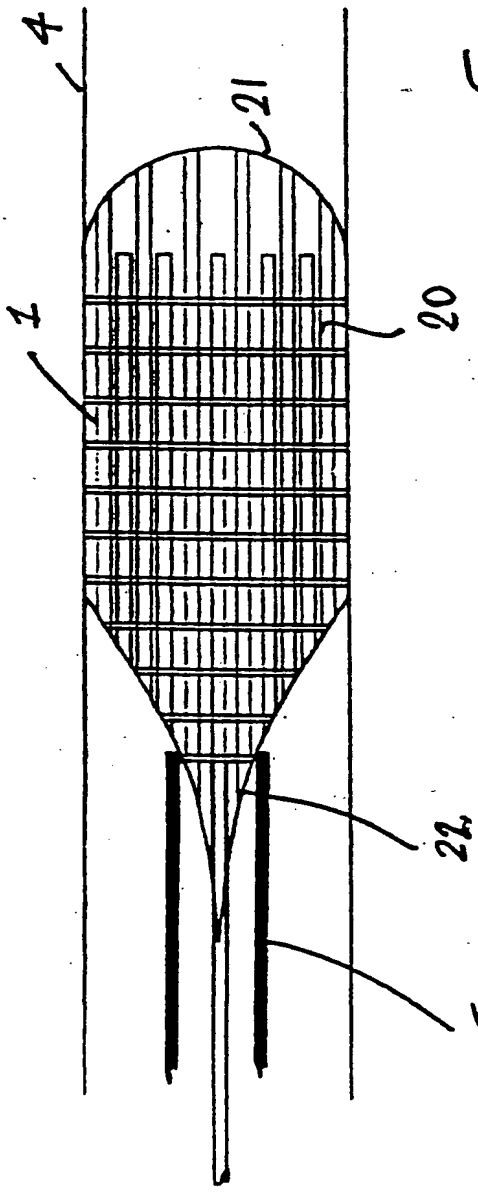


Fig. 10

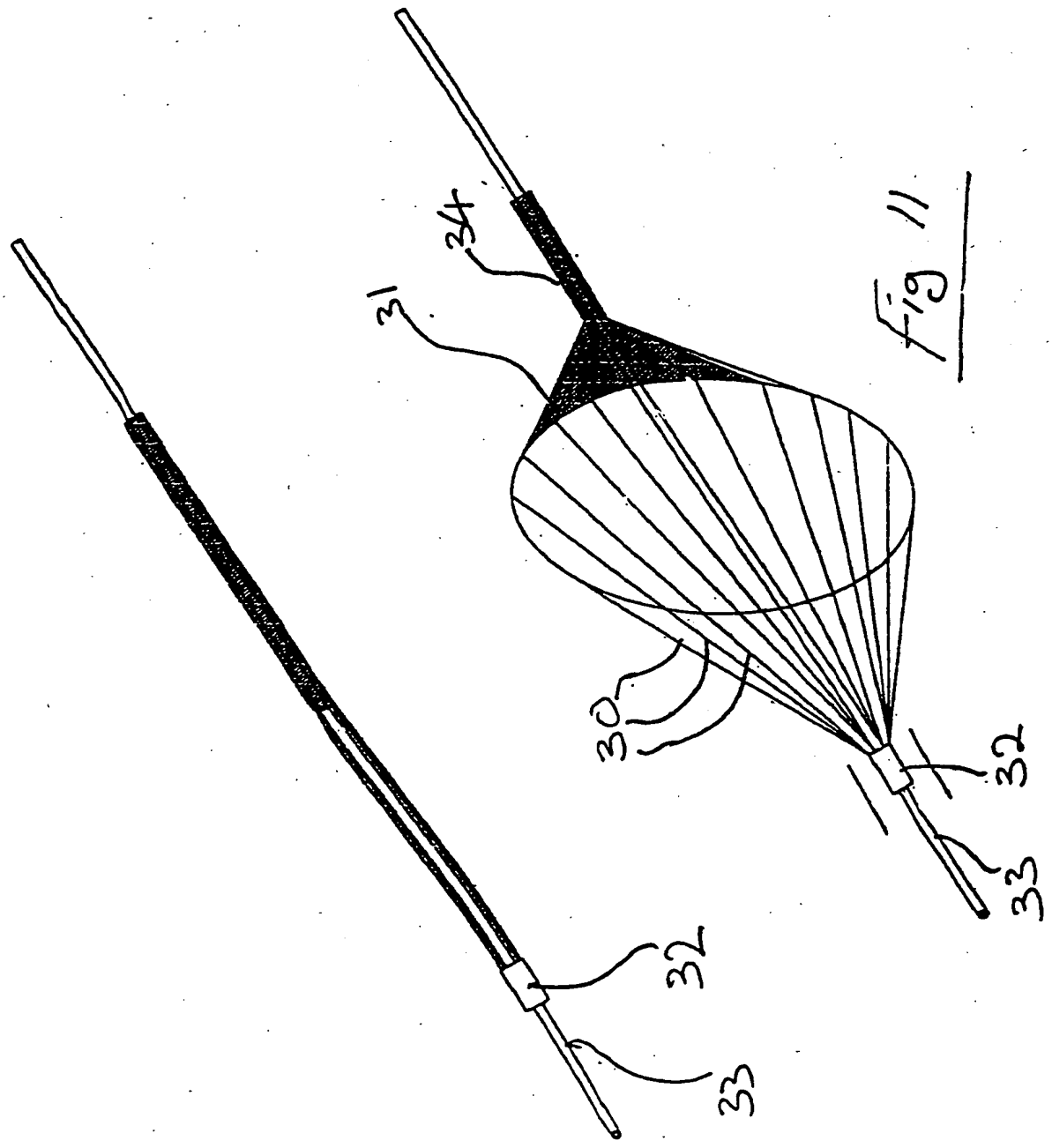


Fig 11

Fig 12

Fig. 13

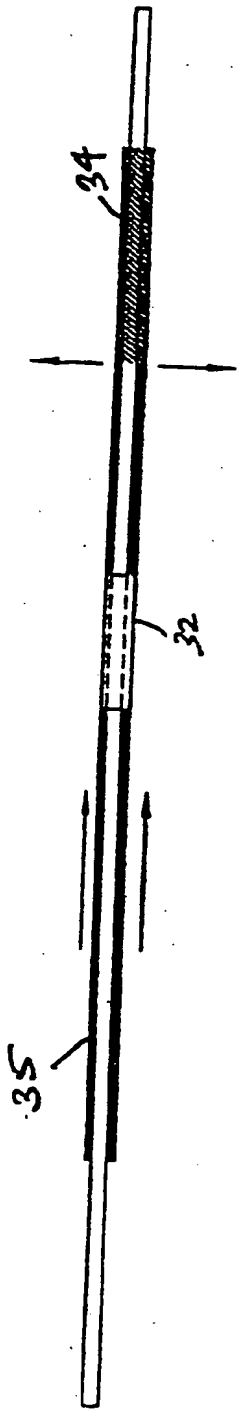


Fig. 14

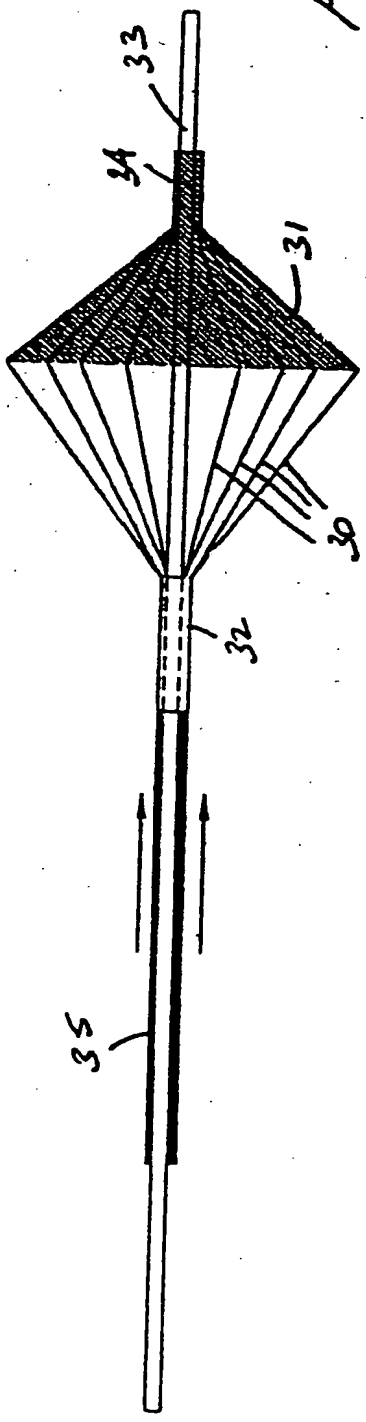


Fig. 15

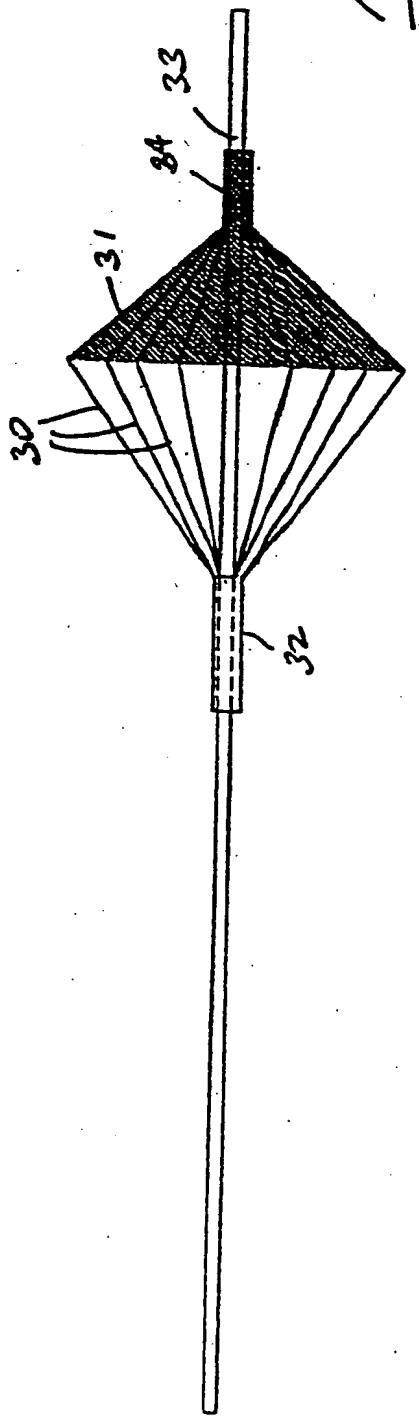


Fig. 16

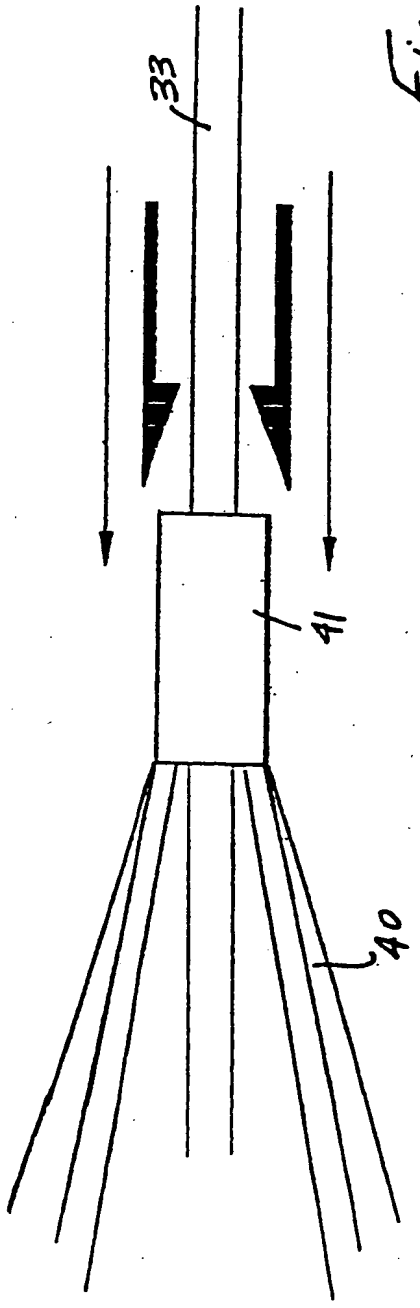
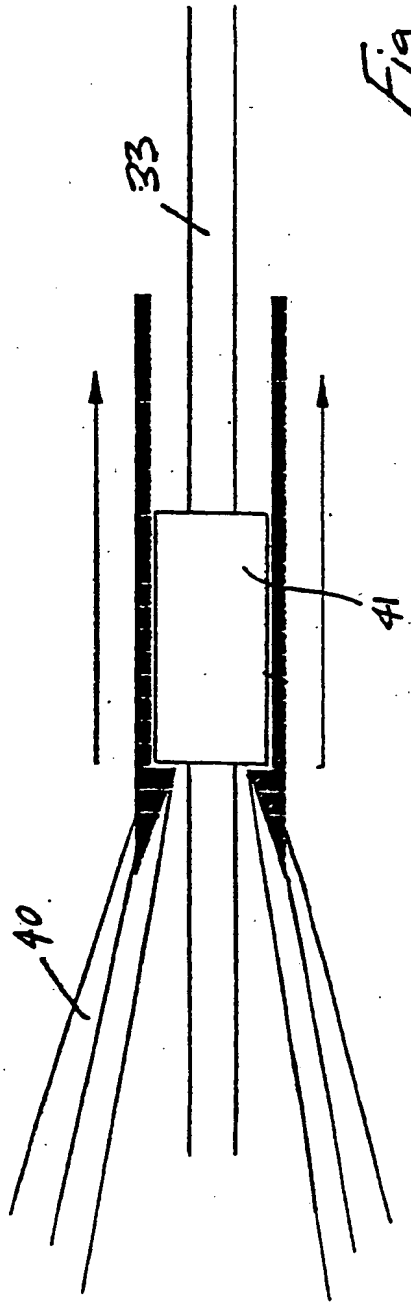


Fig. 17



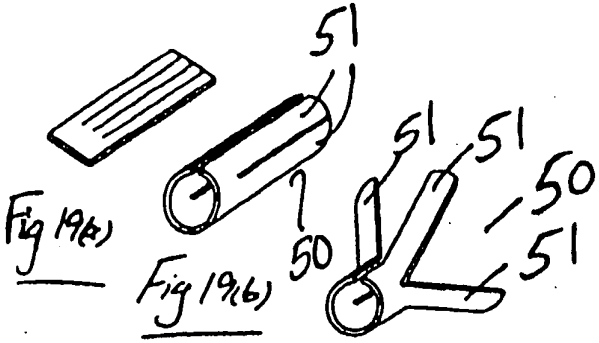


Fig 19(a)

Fig 19(b)

Fig. 19(c)

Fig.18

Fig20

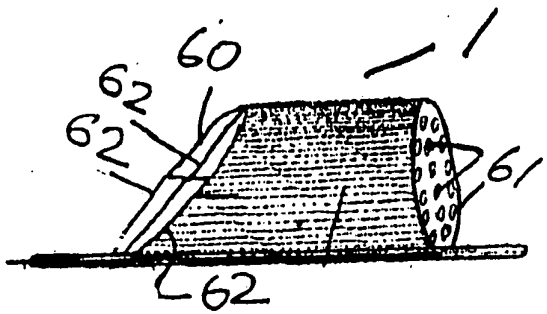


Fig.21

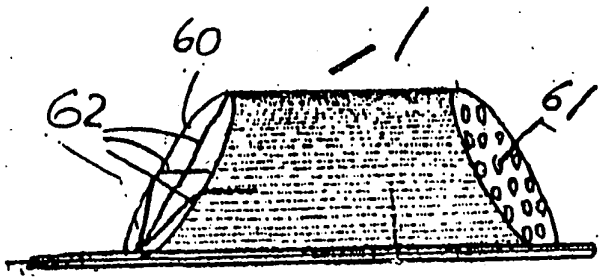


Fig22

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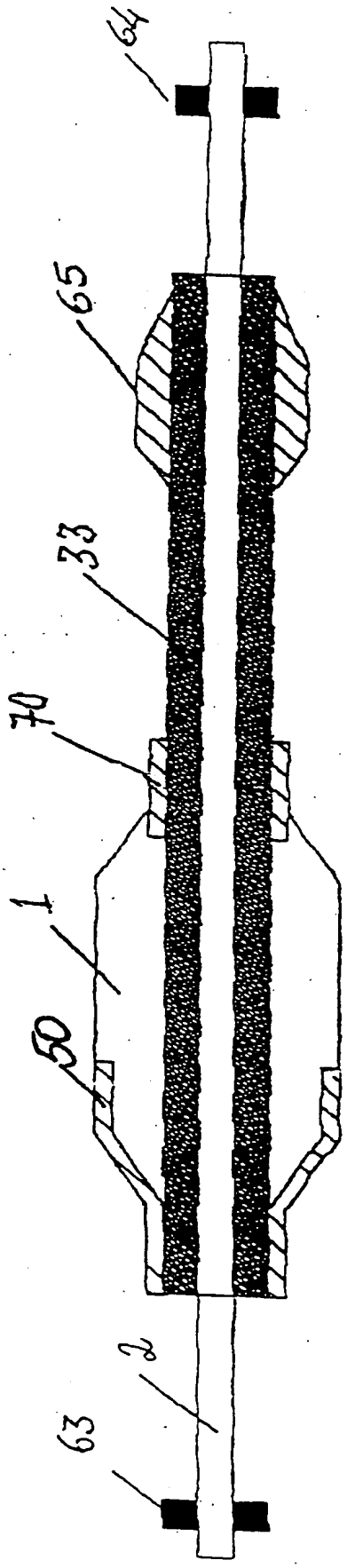


Fig.28

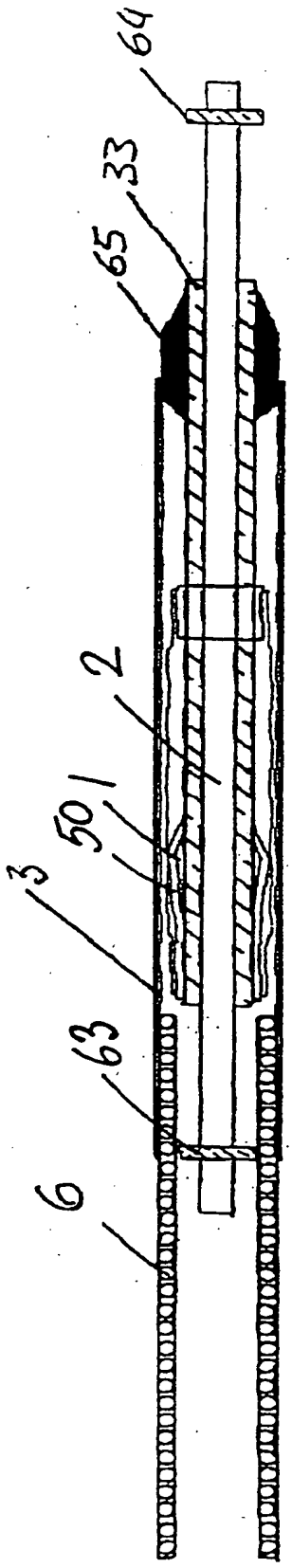


Fig.29

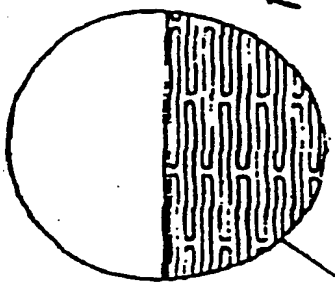


Fig.26

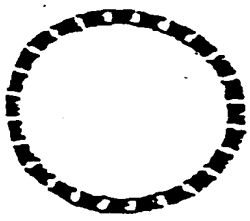


Fig.25

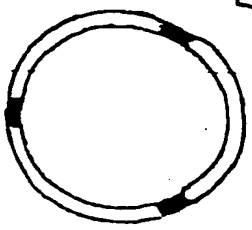
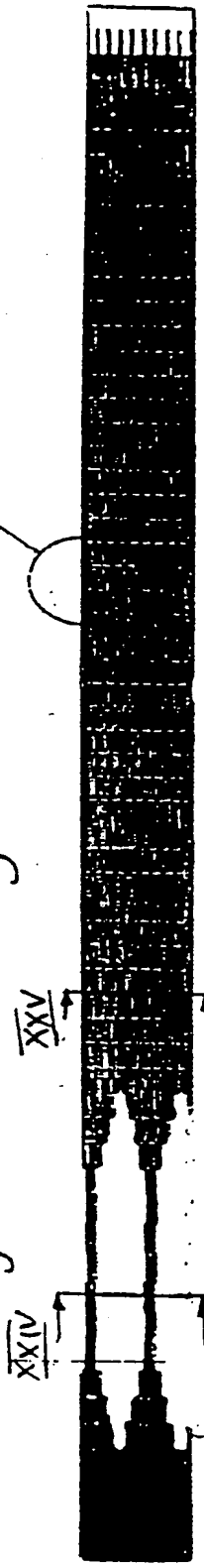


Fig.24



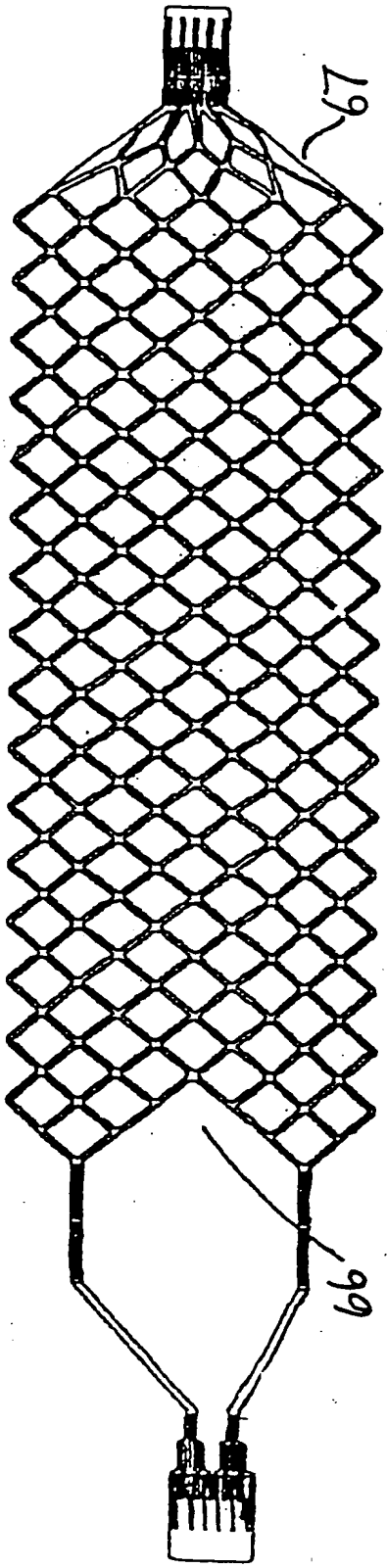


Fig.23

Fig.27

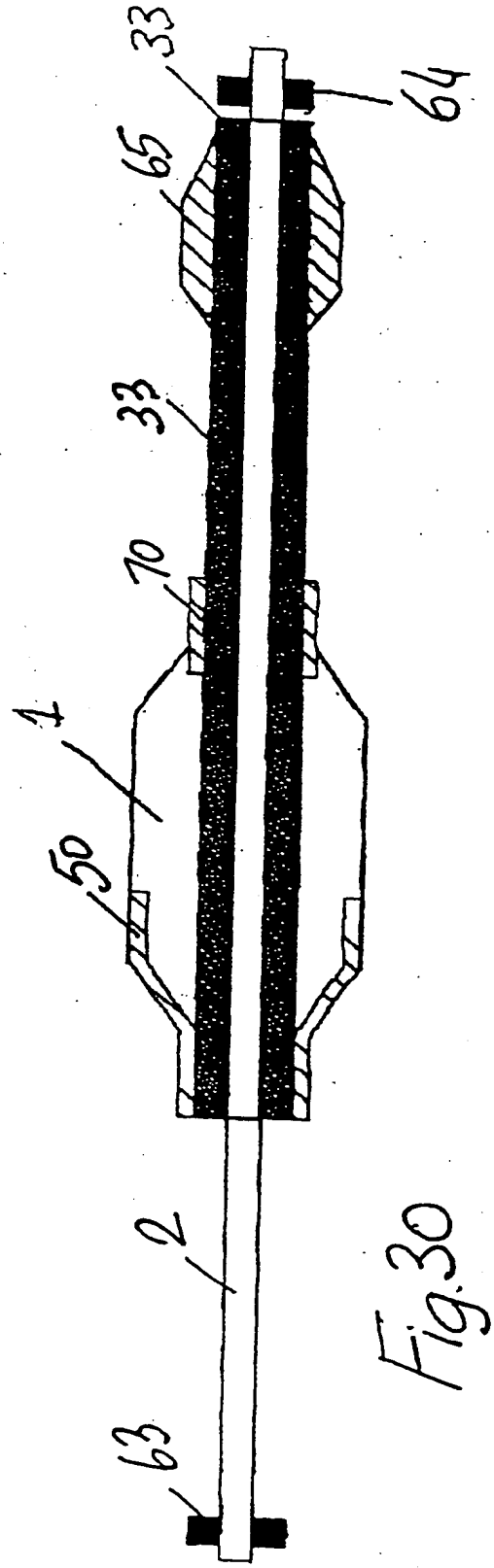


Fig.30

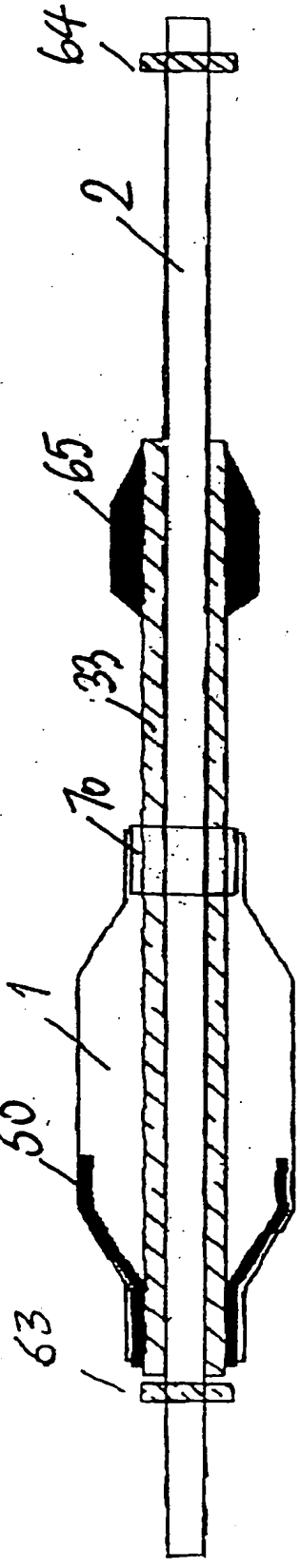


Fig.31

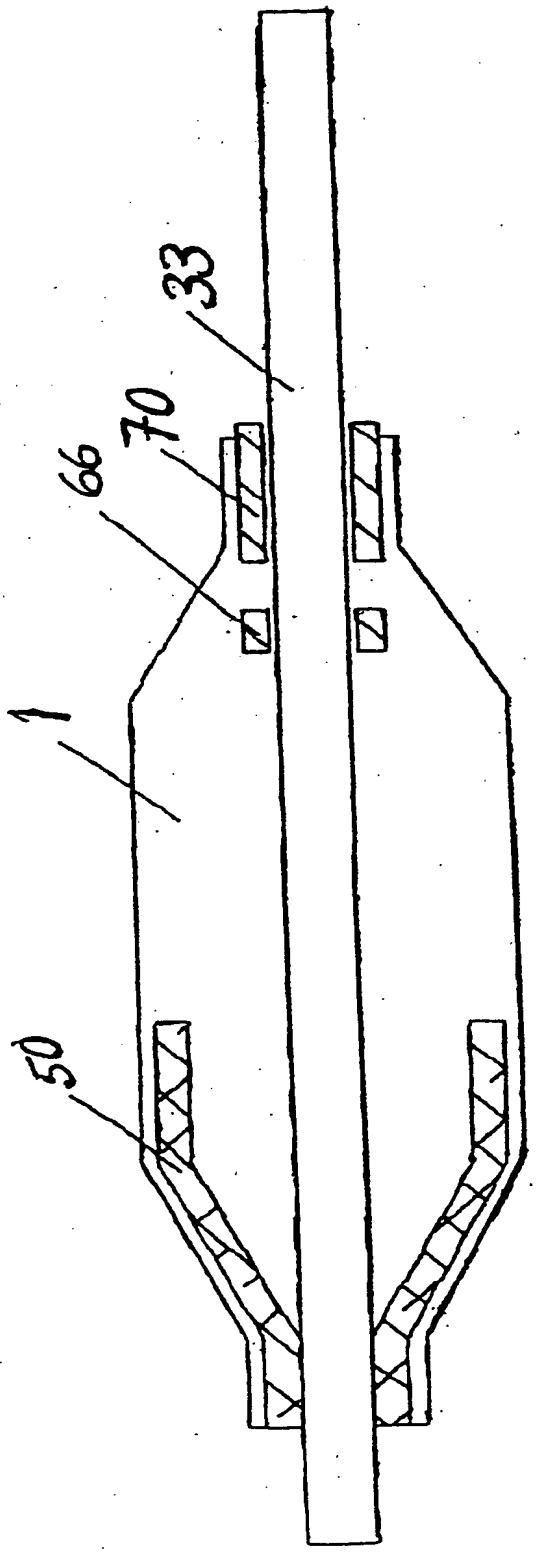


Fig.32

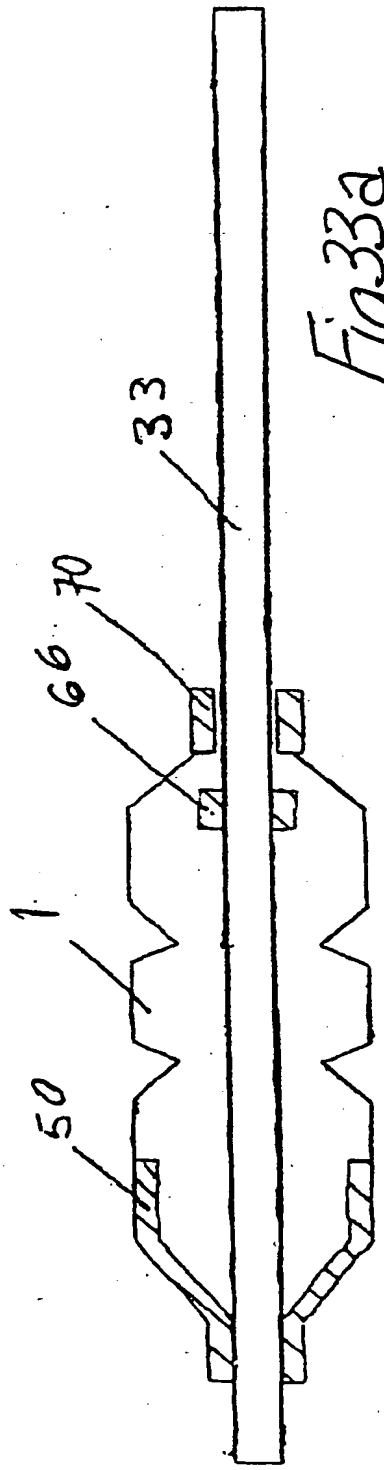


Fig.33a

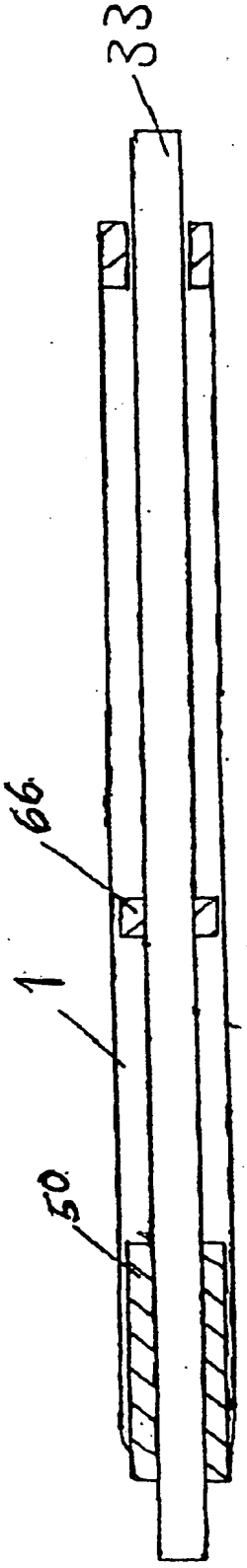


Fig.33b

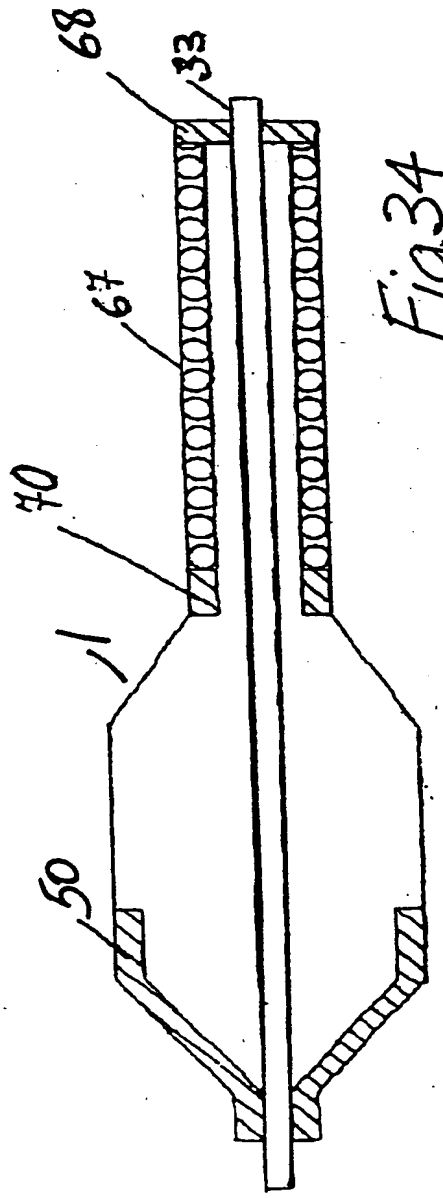


Fig.34

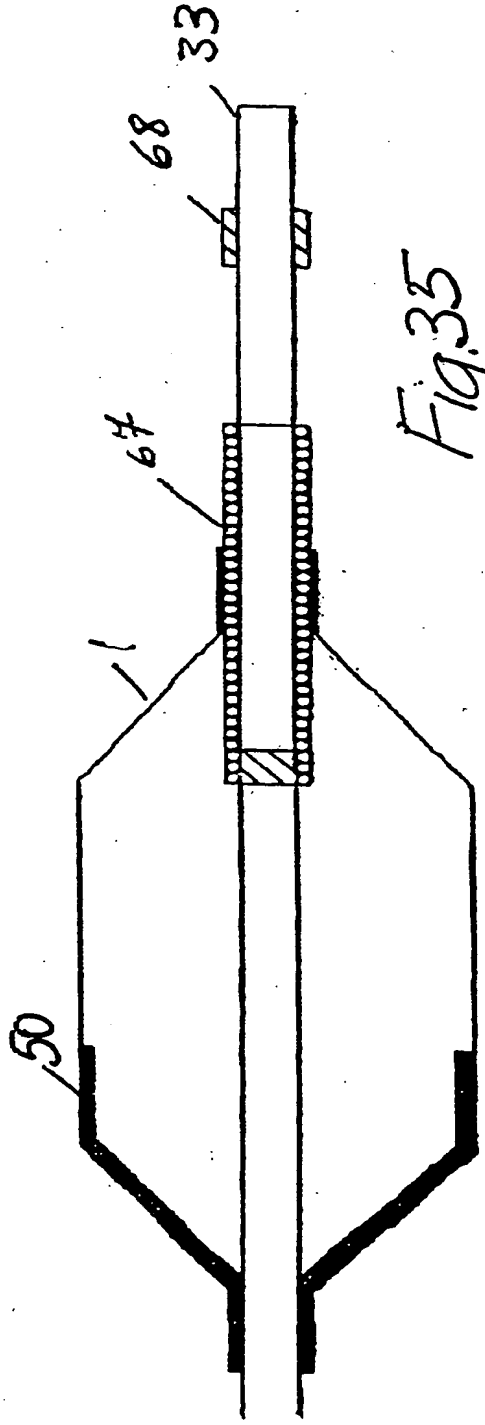


Fig.35

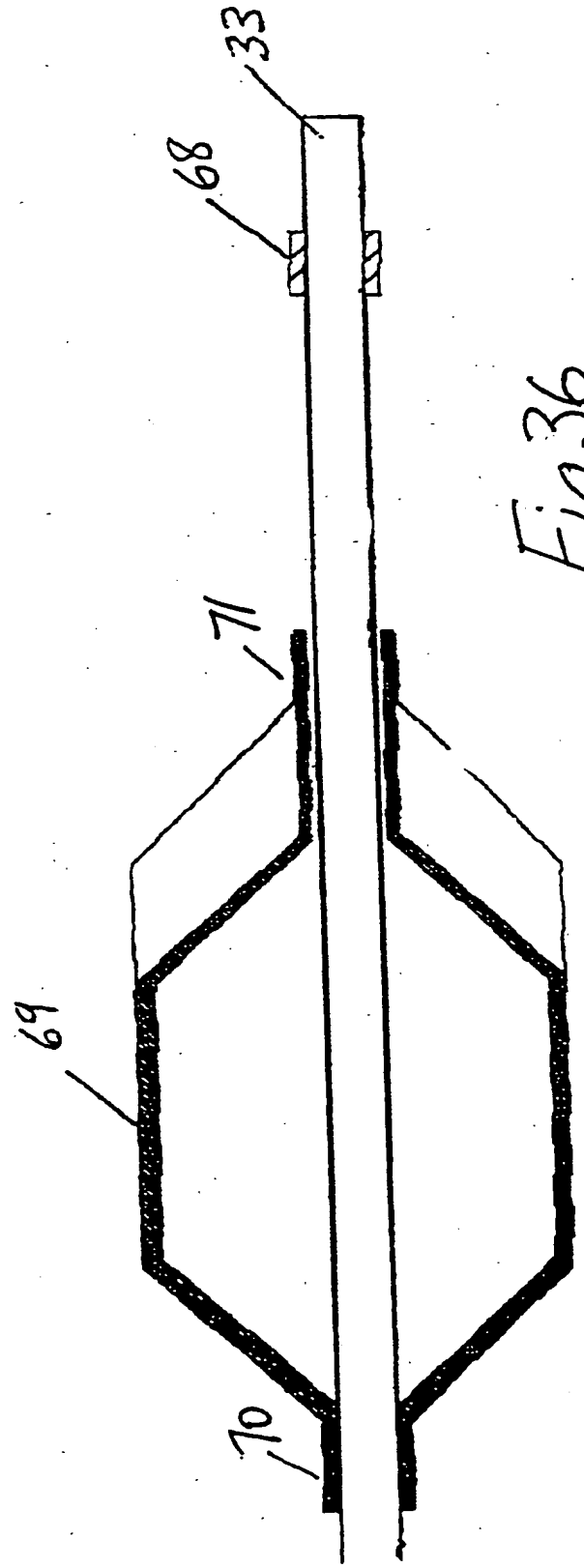


Fig.36

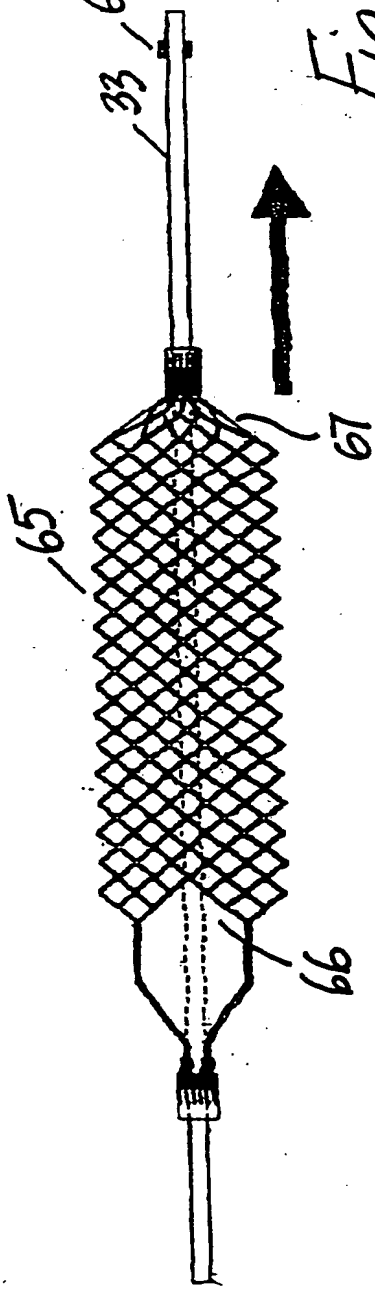


Fig.37a

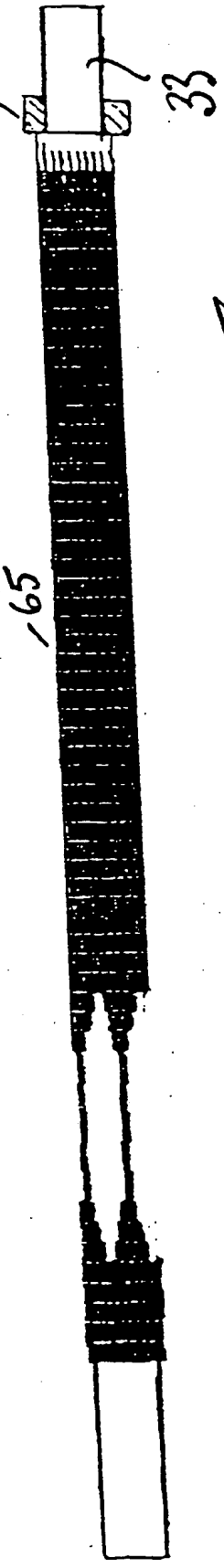


Fig.37b

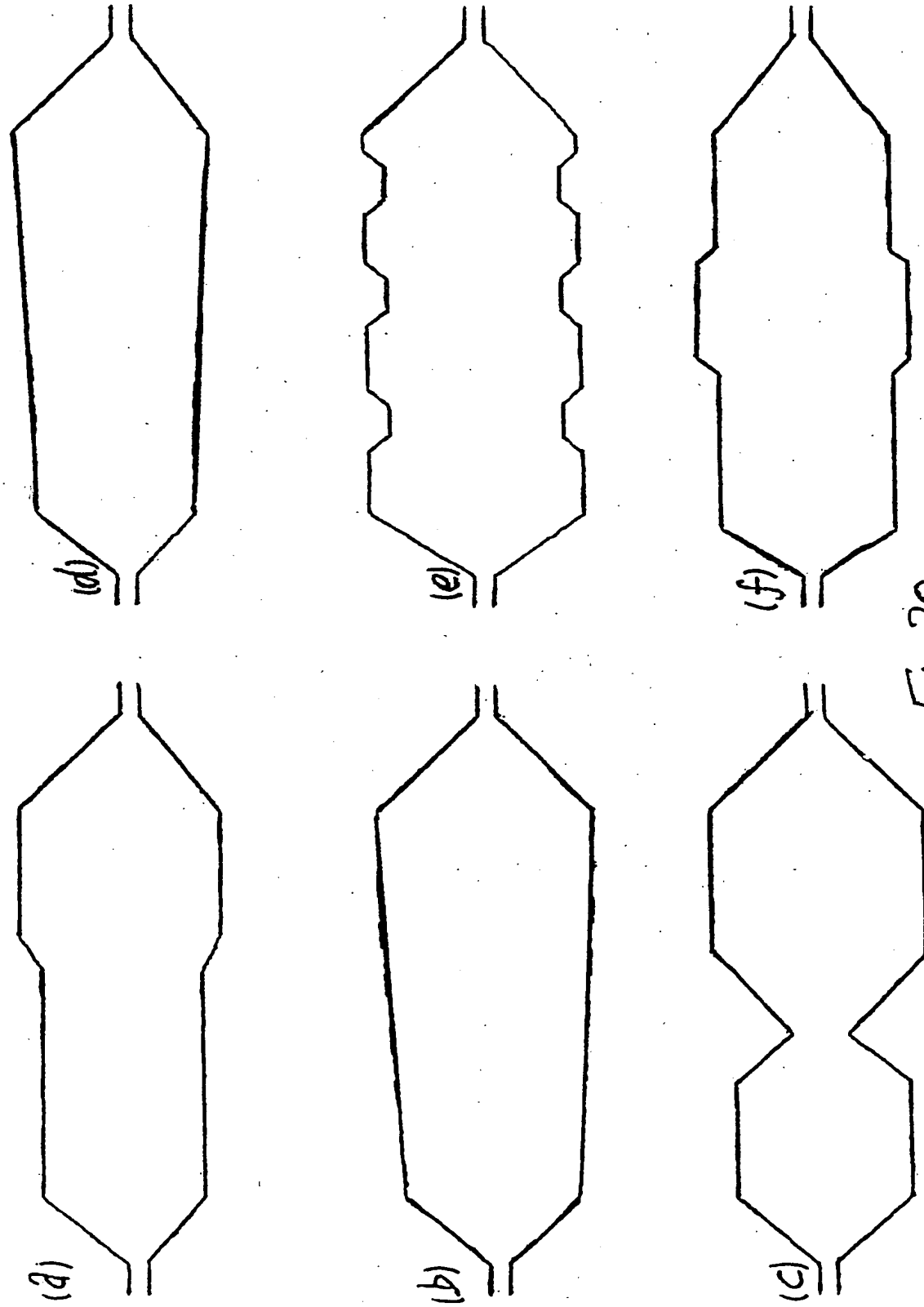


Fig.38

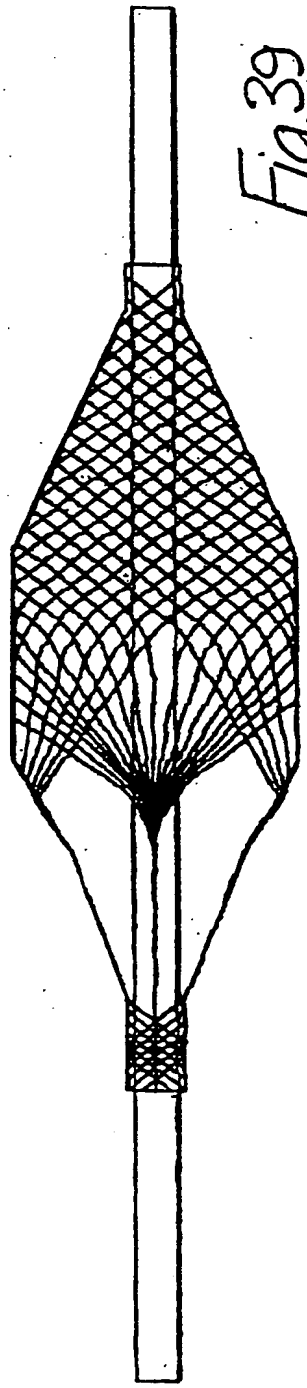


Fig.39

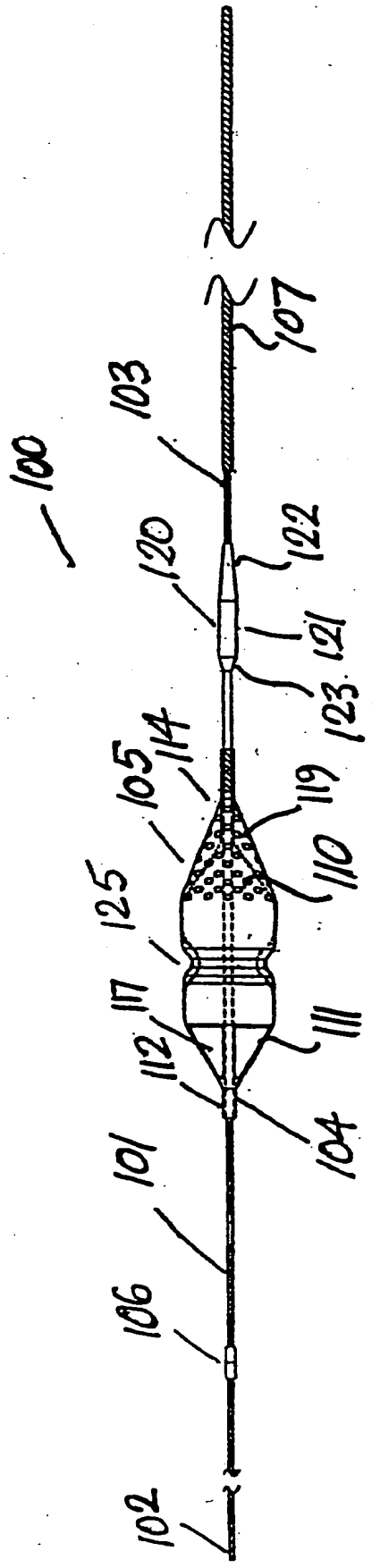

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Fig.40

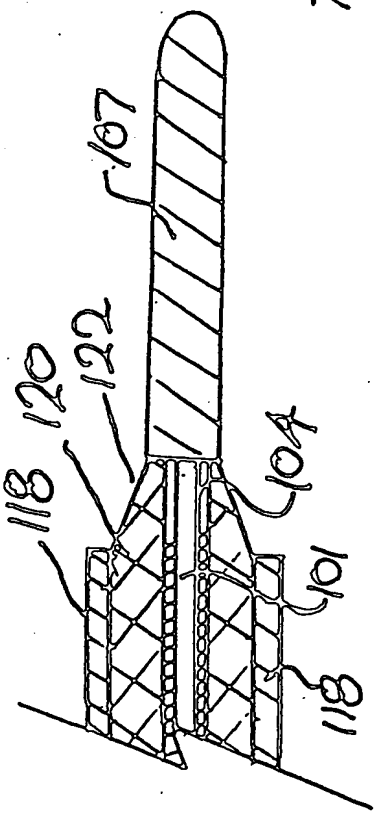
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Fig.42

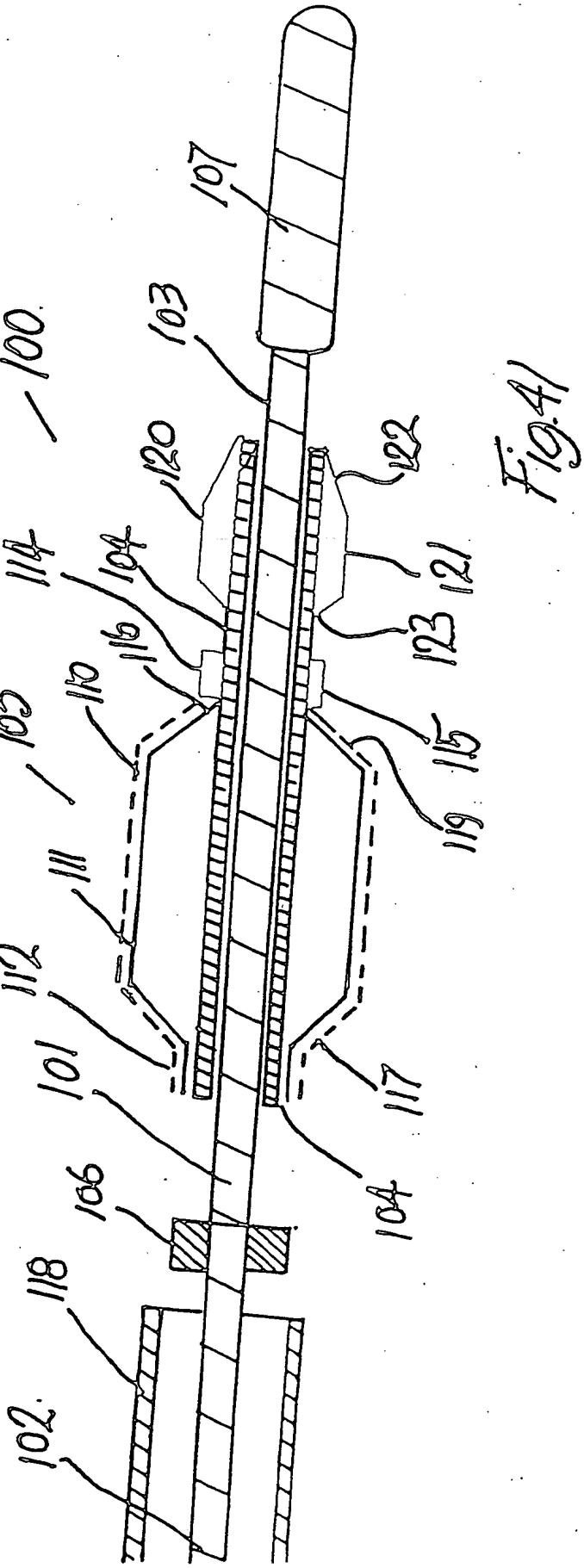
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Fig.41

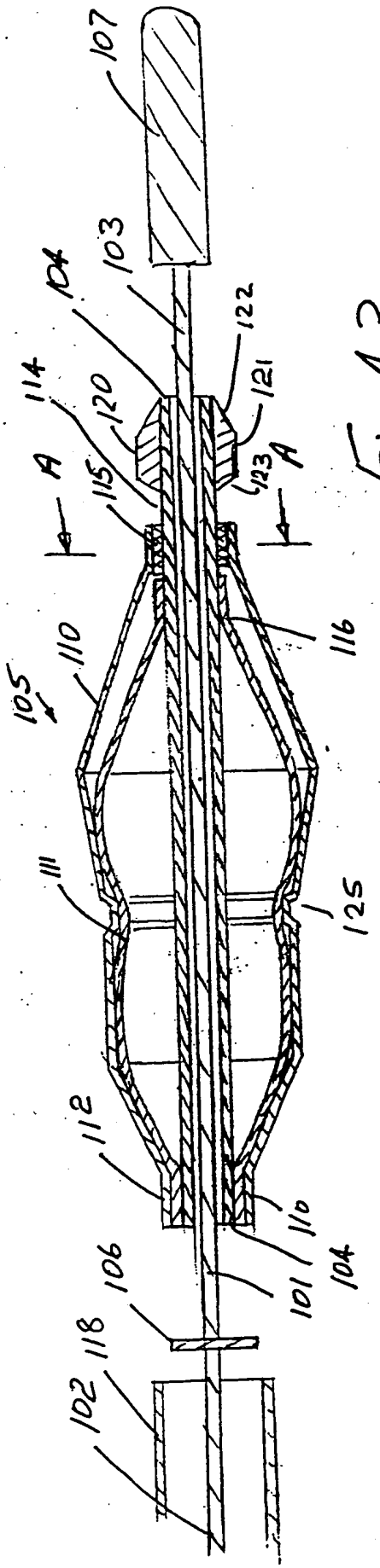

Fig. 43

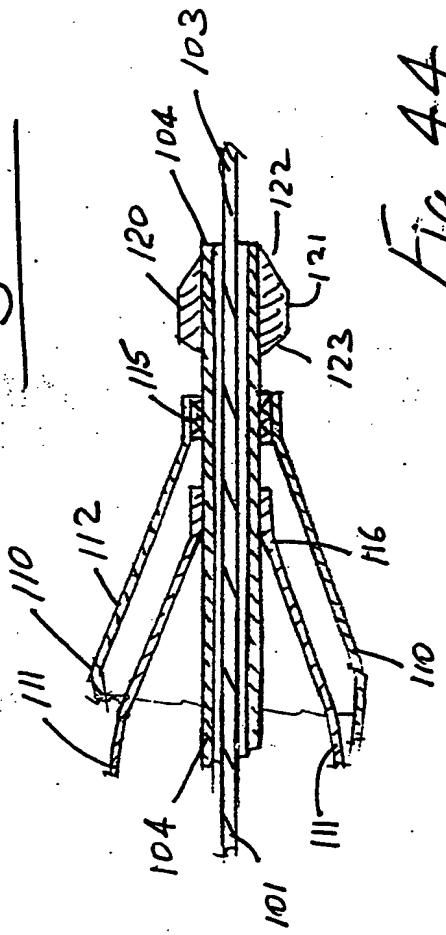

Fig. 44

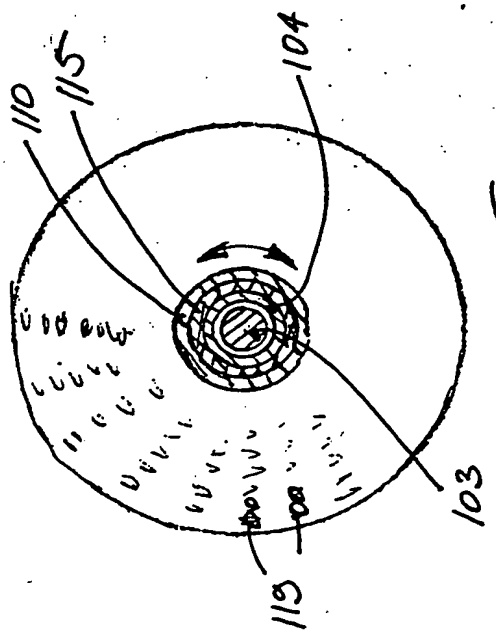

Fig. 45

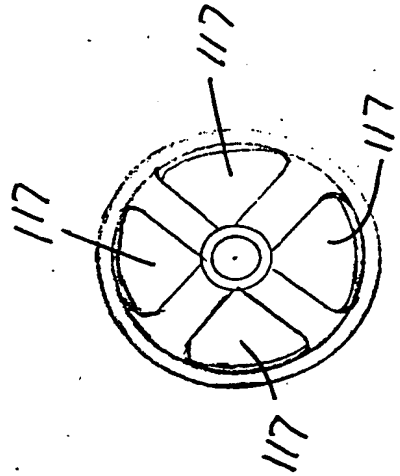

Fig. 48

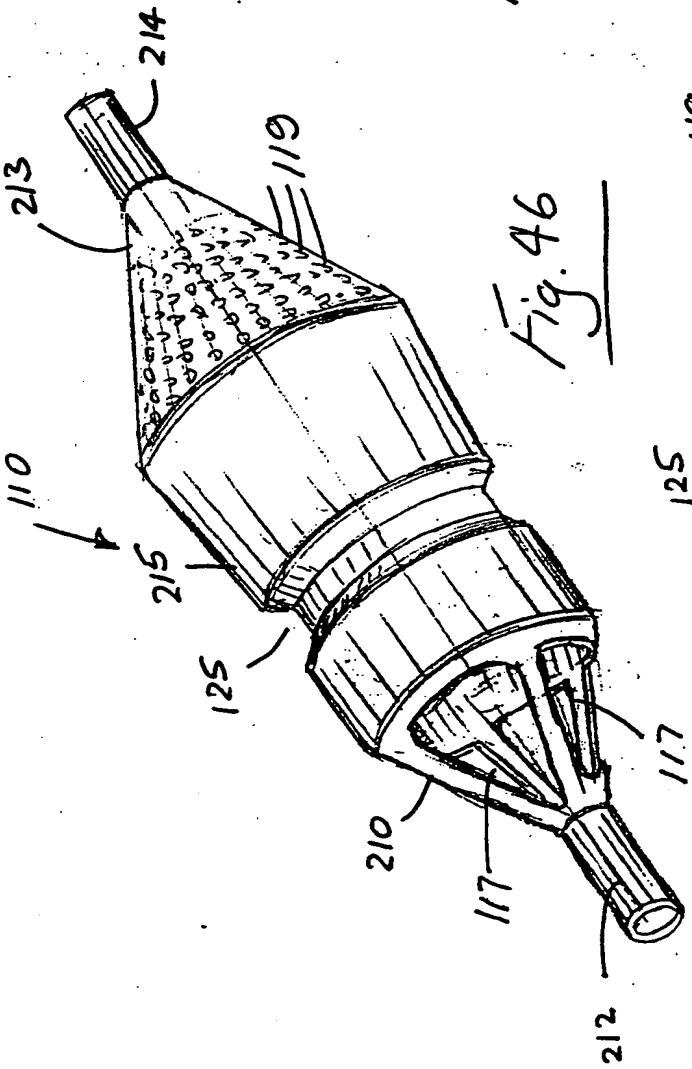

Fig. 46

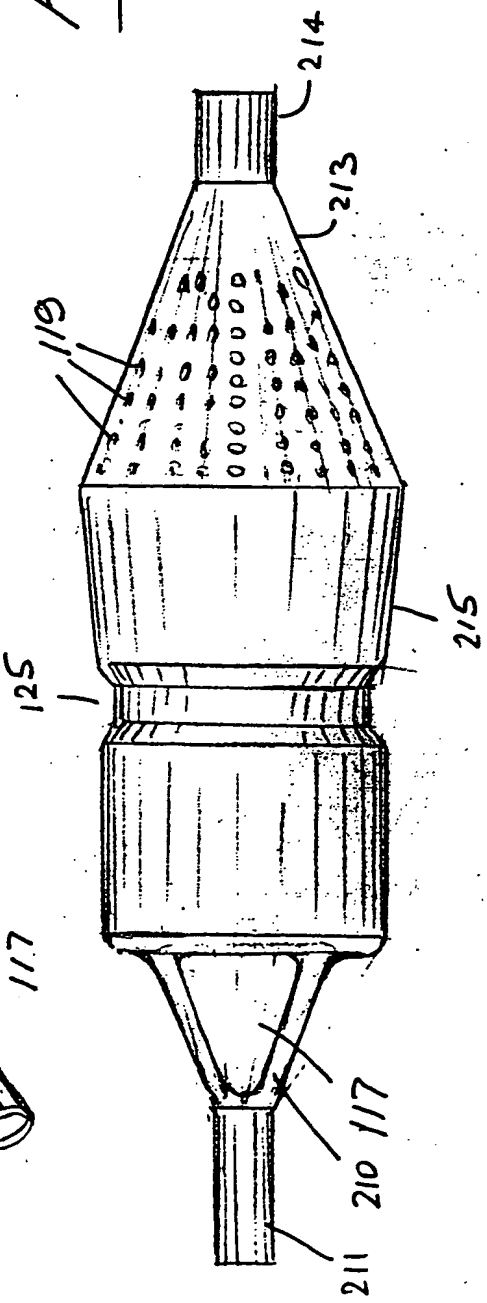

Fig. 47

4
110

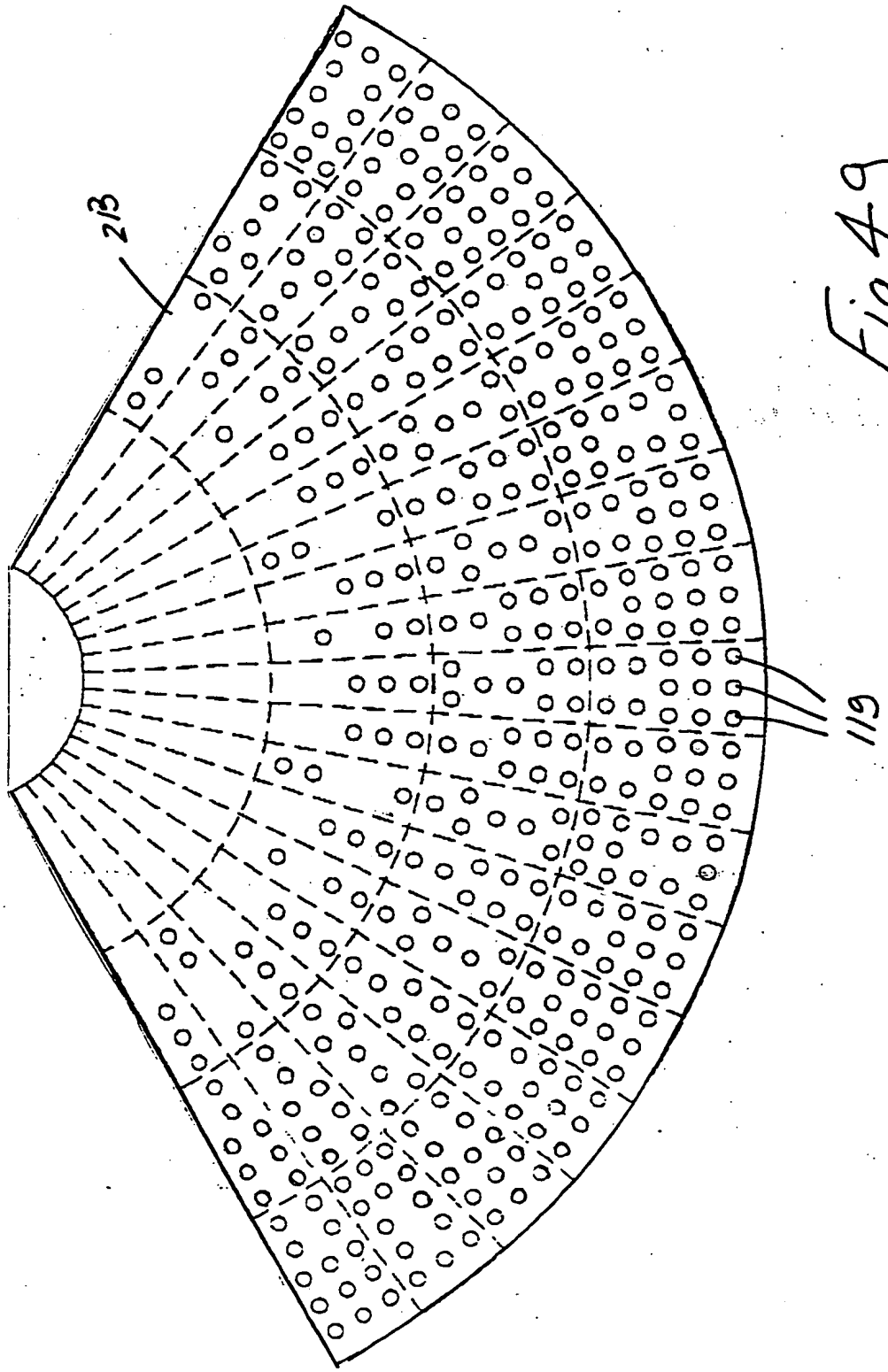

Fig. 49

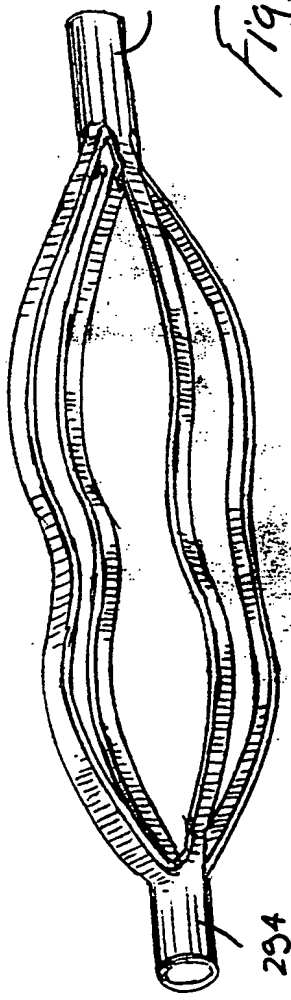

Fig. 50

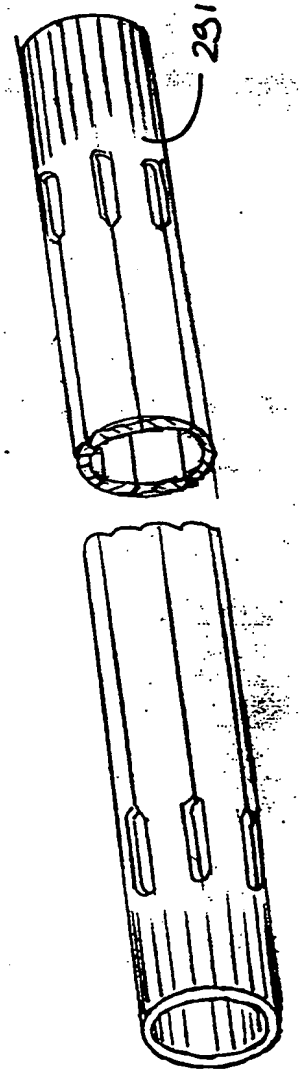

Fig. 52

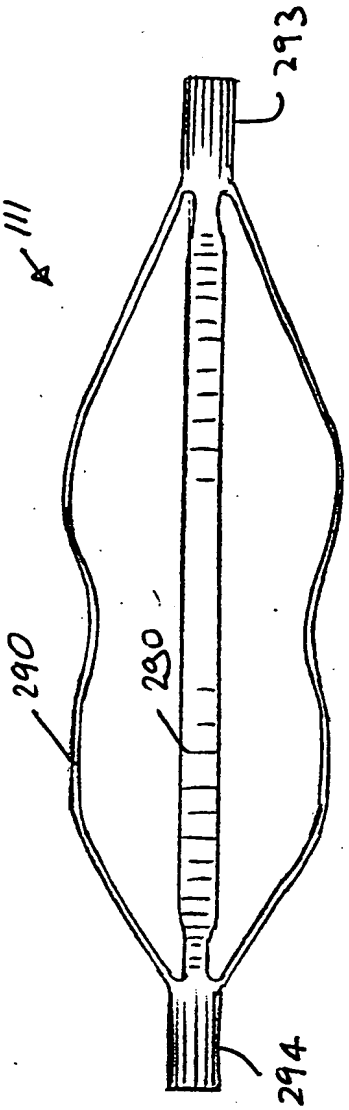

Fig. 51

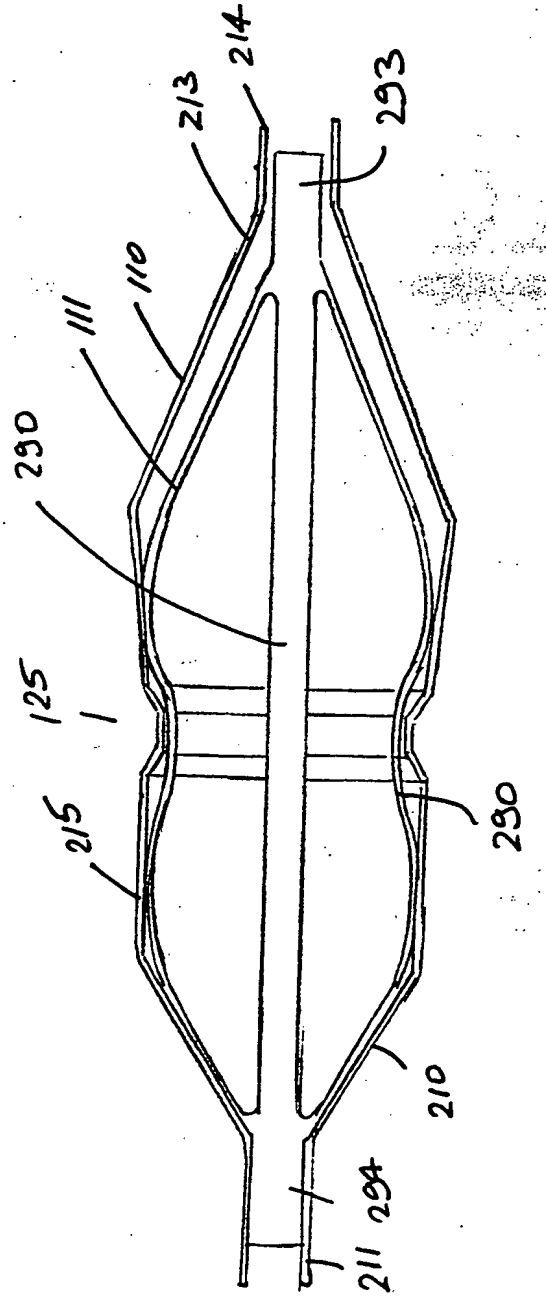

Fig. 53

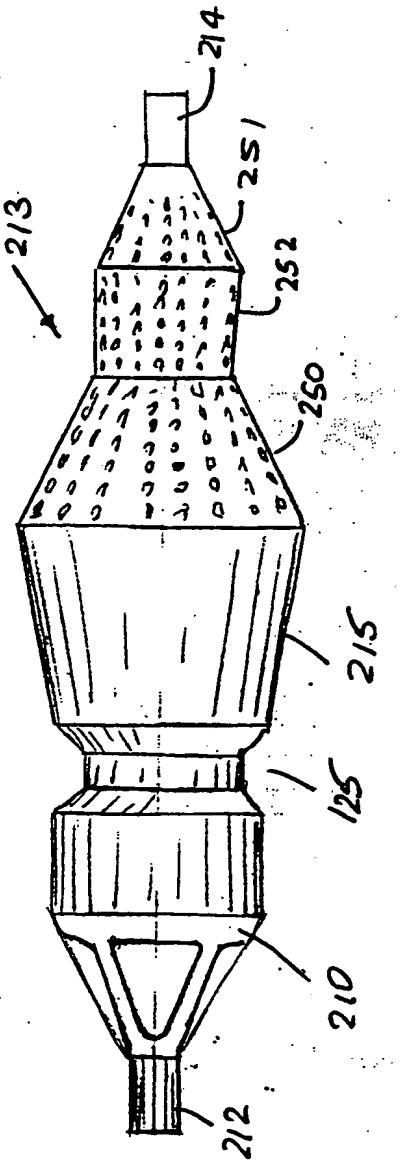

Fig. 54